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MUDRICK, WITT, LEVY & CONSOR W.P.B. FL (561) 659-4155

to coronary disease, but it just helps me quantitate how much a patient has been smoking.

Q. Okay. So there is a thinking among medical professionals that the amount smoked or perhaps how much you smoked for certain units of time might correlate with one's risk for developing a particular disease?

A. Again, I don't know the literature in that regard well enough to be able to say that. To me, I use that more as a means of being able to quantitate how much a person has smoked.

Q. Okay. Do you believe that there is a threshold in terms of how much one must smoke before they would be at risk for developing a particular disease or before they do develop a particular disease in the cardiovascular field?

A. I don't know that data well enough to be able to say.

Q. Okay. Now, let me ask you a general question. If I told you I had just eaten 100 eggs over my lifetime and I stayed away from other sources of cholesterol, would you consider that to be an important risk factor for development of cardiovascular disease in me as an individual?

A. It would depend upon the other factors

of what your native cholesterol is as well. It might be of help, but it would not be an overwhelming strong factor.

Q. If you had a person, hypothetically, with no risk factors for cardiovascular disease in their background and they just smoked, say, 100 cigarettes, in your opinion could 100 cigarettes cause coronary heart disease in an individual?

A. Again, I think you are asking me information that I -- I'm really not -- don't have any expertise in.

Q. Would you be concerned if someone smoked 100 cigarettes, one of your patients, and then quit? Would you tell them that they were at risk or that they would develop cardiovascular disease because of their smoking history?

A. Again, I don't know the scientific data well enough to be able to really say.

Q. I'm speaking now more of common sense advice you might give your patients.

A. I think that would be a reasonable statement

Q. If I told you I just smoked a cigarette a day for one year and then quit, would you advise me that I would be more probable than not to develop

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Page 163

cardiovascular disease because of my smoking?

MR. MIKHAIL: Object to the form.

Depending on what other things?

BY MR. ANDRADE:

Q. Well, I'd like to keep on the same hypothetical: I've lived a perfect life, eliminated all my risk factors for cardiovascular disease. I just smoked one cigarette a day for one year then I stopped. Would you consider that to be — to put me at risk for cardiovascular disease?

A. I don't think it would put you -- this is just purely a conjecture on my part. I don't think it would be a significant risk.

Q. All right. Would you think -- would you advise me that I would more probably than not develop cardiovascular disease based on one cigarette a day for one year?

A. Again, I don't know that data well enough to be able to say anything with any real scientific basis.

Q. Okay. Just based on your clinical experience -- and again, I'm not going to go off the graduation scale. I'm going to stop at this question.

Based on your clinical experience, if I

Page 164 came to you as a patient and I said, Doctor, I'm a smoker. I've smoked one cigarette a day, you know, for 365 days, one year, and then I quit. Am I at risk for cardiovascular disease in your opinion?

A. I would say if you don't do it any more, you probably will not be.

Q. Since you would basically get a smoking history then try to use that information, that ought to give you some idea, roughly, about the degree of risk?

A Yes

Q. And if I came to you and I had a heart problem, say I had coronary heart disease, and you took my medical history and I said, Doctor, I may have some other risk factors in my background, and I give you good information, accurate information, about diet, blood pressure, so on and so forth, but I also told you I smoked, say, just 100 cigarettes, no more, would you be of the opinion that the cigarette smoking was the cause of my heart disease in that case if I had other risk factors in my background?

A. I can't say that but I would tell you again, Don't do it anymore.

Q. Sure.

A. And that would lessen your risk.

Q. Have you ever seen a patient who just smoked a few cigarettes whose disease you would attribute to their smoking? Have you ever seen a patient who smoked, again, just maybe 100 cigarettes, for a round number, whose cardiovascular disease you would attribute to their smoking?

 All I can tell you is I have seen people who smoked a very little who still had some coronary disease, but I cannot necessarily attribute one or the other because I don't know -- again, I'm not familiar with that data.

Q. Okay. But no one who smoked just as few as, say, 100 cigarettes?

A. I would think that would probably be

Q. I wanted to ask you a question about something we discussed just before the break. You had mentioned earlier that your personal practice consisted of approximately 5 percent Medicaid patients.

A. No. I think what I said was it was less than 5 percent.

O. Excuse me. Less than 5.

Yes.

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Q. That's why I'm trying to use the word "approximately." Less than 5. And your opinions are based predominantly on your clinical experiences?

A. That's correct.

Q. Okay.

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Do you believe that one can apply clinical experiences from a patient -- based on a patient population of less than 5 percent Medicaid patients to a population of exclusively Medicaid patients?

MR. MIKHAIL: Object to the form. THE WITNESS: With reference to coronary disease?

BY MR. ANDRADE:

Q. Yes. Your general experiences with respect to cardiovascular disease and all the risk factors, do you think that one's clinical experience based on a population of 5 percent Medicaid patients, or less than 5 percent, would be directly applicable to a population of 100 percent Medicaid

A. I would have to say two things: One is, if when you say cardiovascular disease if you mean specifically coronary heart disease. And my

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clinical impression, from what I see, is that the disease process in both populations would be the same.

Q. Could you repeat that, please.

A. That the disease process itself would be the same and so I -- you perhaps could, but I don't see that much difference in the -- once the disease is manifest, I really don't appreciate much difference between Medicaid and non Medicaid. I don't appreciate any difference in the disease process in those two groups.

Q. But you would agree that in your

practice you have a fairly high percentage -- I think you said approximately 40 percent or so -- of elderly patients?

A. Yes.

Q. And in that respect your patient population might differ from a Medicaid population since the Medicaid recipients, I believe once they reach age 65, they would qualify for the Medicare program?

A. Yes. Again, but still a heart attack is a heart attack.

Q. Sure. But just in terms of the differences between your patient population in your

Page 168 practice and a purely Medicaid population of patients, your practice would be different because you would have approximately 40 percent elderly people in your practice?

A. The demographics are different but the disease is the same.

Q. Sure. Whether you're old, poor, or wealthy, one can always develop coronary heart disease or peripheral vascular and so on?

A. That's correct.

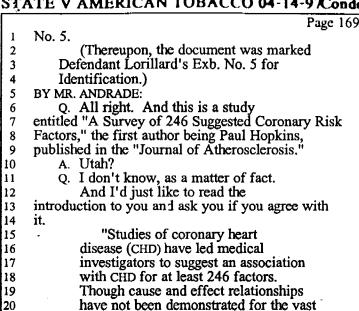
Q. But in terms of the demographics, your patient population would be different from the Medicald population since you would have 40 percent, approximately, of elderly patients in your population and you wouldn't have these in the Medicaid population?

A. That's correct.

Q. And you would also have, I think you said, although you couldn't put a percentage figure on it, a pretty good percentage of affluent people in your population of patients which wouldn't be in a purely Medicaid population?

A. That's correct.

Q. I wanted to show you a study, Doctor. I'll have it marked as, I guess, Defendant's Exhibit



majority, consideration of these

factors provides clues to CHD etiology

Would you agree with that statement?

and insight into possible preventive

MR. MIKHAIL: If you need time to look at the article, feel free to do that. THE WITNESS: Well, I really can't make a comment if I agree because I don't know what factors they are referring to. So I would have to look at the whole body. BY MR. ANDRADE:

O. Okay.

Would you agree that there are many risk factors for coronary heart disease?

A. Yes.

Q. I think I asked you to identify those risk factors, that you could, for coronary heart disease and you listed approximately five or six before the break, if my memory is correct.

That's correct.

Q. Right. And I just wanted to ask the question: Would you basically agree that there are many risk factors of coronary heart disease?

A. There are many risk factors; whether there are 246, I would have to look at these.

Q. All right, let me do it this way: Let me ask you some questions on some other risk factors and see if you would agree.

Cholesterol levels, would they be a

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risk factor for coronary heart disease? And I'm not referring to the paper any longer.

A. Okay.

measures."

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Q. Let me start again. Would cholesterol levels be a risk factor for coronary heart disease?

 A. Yes. But you have to qualify that a little bit. Because if you have other risk factors independent of hypercholesterolemia such as smoking, positive family history, in those situations what the cholesterol is, if you have -- if you are a nonsmoker with no family history, your cholesterol can be higher without an increased risk; if you are a smoker, it takes a lower value before there is really an increased risk, so I have to qualify that a little bit.

Q. Were you aware of studies that control for other risk factors for cardiovascular disease, including coronary heart disease, that still report that cholesterol level are an independent factor for coronary heart disease?

A. Yes. That's correct.

Q. So if you had a population with no other coronary heart disease risk factors in their background but had high cholesterol levels, that would be a risk factor for coronary heart disease?

Page 172 A. That's true. But I also have to add the caveat, and that is, for example, if you are a smoker, the cholesterol that is really acceptable is lower if you are a smoker than a nonsmoker because of the risk.

Q. Doctor, I'm not asking you about any kind of potential interaction among risk factors. I'm asking the simple question: Is coronary heart disease -- for coronary heart disease, is cholesterol levels a risk factor independent of other factors in the sense that studies have controlled for those other factors and held them constant?

A. That's correct.

Q. Okay. Thank you. How about diabetes, is that a risk

factor for coronary heart disease?

A. Yes, it is.

Q. And obesity?

A. Yes, it is.
Q. Personality type, so-called type A personality?

A. That's -- I think that's questionable.

Q. Can I ask why you question those studies that report that type A personality is a

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risk factor for coronary heart disease? A. That was much more popular maybe 20, 25 years ago. And I think now maybe people are looking at that population and there may be a subset of that group who may constrict their coronaries under periods of stress. There -- it may be a risk factor but I don't think the association is quite as strong as it was assumed to be a number of years ago. Q. Stress itself has been reported to be a

risk factor for coronary heart disease? A. Yes.

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Q. And exercise, lack of exercise, is a risk factor for coronary heart disease?

A. Then you are starting -- you're starting to get into more of an association than a risk factor.

Q. Do you believe --

A. Because some of those are difficult to

Q. Do you believe that there are some individuals who, because of their lack of exercise, are at greater risk for coronary heart disease, all other factors being equal?

A. That literature I do not know well enough to comment on.

Q. All right, Do you advise your patients to take regular exercise?

A. Yes.

Q. If they have a sedentary lifestyle, do you advise them to do something three or four times a week to get their cardiovascular rate up?

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A. Yes. I know that they can reduce the risk by exercising regularly. But conversely, I don't know that a lack of exercise may contribute to the development of coronary heart disease.

Q. Is your concern that there are so many risk factors that may play a role for coronary heart disease that it's very difficult to extricate them?

MR. MIKHAIL: Object to the form.

Extricate them from what? BY MR. ANDRADE:

Q. From each other.

A. I think there are certain risk factors in which the association is weak. And as we talked about age earlier, that there may be an association but I would -- I would hate to put it down as a cause. And -- but I think if you are talking about the major risk factors, then I think you can extricate some of those from the others.

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Page 175 Q. All right. But it is not your opinion that there is no literature on some of these risk factors such as Type-A personality or age that do report a statistically significant increased risk for coronary heart disease and those risk factors?

A. I'm a little -- if you could simplify your question.

Q. It's not your testimony, is it, that there are no scientific studies that suggest that factors such as age and Type-A personality have been associated with an increased risk for coronary heart

 A. What I am saying is there have been some people that have suggested that.

I got lost in the double negatives

Q. Have they suggested that in scientific studies?

A. Yes

Q. Did you consider cardiovascular disease, and specifically coronary heart disease, to be a multi factorial disease?

A. It can be. It not always is, but it

Q. There may be some individuals who only

Page 176 have one risk factor in their background that could account for the coronary heart disease?

A. That's correct.

Q. And there are some other individuals who may have many risk factors, some of them you have identified here today, that also might play a role in the combination in the development of coronary heart disease?

A. That's correct.

Q. When a patient first comes to you complaining of, say, chest pain, do you normally take a medical history of that individual?

A. Yes.

Q. And do you ask that person about risk factors that are in their individual background for coronary heart disease?

Yes, I would.

Q. And what would be some of the questions that you would ask a patient like that?

A. Do you smoke? Are you a diabetic? Have you been hypertensive? Is there any premature coronary disease in your family?

Q. Anything else of interest that you would question them on?

A. Those would be the major things.

<u> </u>	TIL V ZMARKETAN TODITOGO VI IV S/COM
Ī .	Page 177
1 2	Q. Would you be interested in their cholesterol levels?
3	A. Yes.
4	Q. Would you be interested in observing or
5	maybe measuring the weight of the individual if they
6	appeared obese to you?
7	A. Yes.
8	Q. Okay. Would you be interested in
9	family history? Did you identify family history?
10	A. Yes, I did.
11	Q. Would you be interested in other
12	information about sedentary lifestyle versus
13	somebody who does a lot of physical exercise? Would
14	that be important for you to know?
15	A. It's important but I don't think it
16	really sways my diagnosis one way or the other.
17	Q. Would you be interested in the
18	magnitude of high blood pressure?
19	A. Yes, I would.
20	Q. So you would be interested if they did
21	have hypertension; is that right?
22	A. Yes.
23	Q. And you would probably have some
24	interest in the level of hypertension?
25	A. Right, and how well controlled it was.
	*** No

Q. Okay. And that would be true for cholesterol levels as well?

A. Yes.

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Q. Would you also be interested in whether or not they are compliant with medication that may have been prescribed for, say, high cholesterol levels or high blood pressure?

A. Yes.

Q. Do you find that patients sometimes are less than straightforward in terms of self reporting information about their backgrounds?

A. With regard to?

Q. Well, for instance, with regard to

compliance with medication?

A. I think basically most people are fairly honest. I mean, obviously, there are some people that that is going to be a problem with but I don't think that's an overwhelming issue.

Q. When individuals report to you that they have these risk factors in their backgrounds, I think you mentioned earlier, that you do counsel them or advise them to try to reduce or eliminate those factors; is that correct?

A. Yes, Í do.

Q. So if I came to you and I was a smoker,

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Page 179 you would advise me to stop smoking? 2 A. Yes, I would. 3 Q. If I -- I need some other hypothetical. 3 If I came to you and if I was overweight considerably, you would advise me to lose weight? 5 6 Yes, I would. 6 Q. If I had high blood pressure, you might 7 7 even prescribe some medicine for me to treat the 8 9 high blood pressure? 9 10 A. That's correct. 10 11 Q. And for other things I could do to 11 12 reduce it, you would probably recommend those to me |12 13 as well? 13 14 A. Yes, I would. 14 15 Q. All right. And the same would be true 15 for other risk factors for cardiovascular disease or 16 17 coronary heart disease that you could detect in a 17 18 person's background: If there is a way of modifying 18 19 them or eliminating them you would offer that advice 19 20 to the patient? 20 21 A. Yes, I would. 21 22 Q. All right. I think earlier you 22 23 mentioned that you may have seen in your practice 23 only two individuals in your career who had coronary 24 heart disease but no risk factors in their 25

Page 180 background for coronary heart disease; is that correct?

A. That's correct. That would be an approximation. I would just say it's exceptionally

MR. MIKHAIL: You all referred to this article as an exhibit but it didn't have a sticker on it. Is this the one that is to be

MR. ANDRADE: Yes, I guess. I apologize. I may have given it to you before having it marked. I'll take care of that.

MR. MIKHAIL: Thank you.

BY MR. ANDRADE:

Q. Doctor, I'd like to hand you another article entitled, "Identification and Relative Weight of Cardiovascular Risk Factors." Again, the lead author is Dr. Paul Hopkins. This was published in, if I could find the name of the journal, "Cardiology Clinic." And I'd like to have it marked Defendant's Exhibit No. 6.

Thereupon, the document was marked Defendant Lorillard's Exb. No. 6 for Identification.)

BY MR. ANDRADE:
Q. I would like to direct your attention if I could to the first page, the left-hand side, the second full paragraph. I would like to read it to you and ask you if you agree with it.
"The most important risk factors

"The most important risk factors for cardiovascular disease include age, sex, strong positive family history, cigarette smoking, systolic and diastolic hypertension, plasma levels of total and high density lipoprotein (HDL), cholesterol, diabetes and obesity. Some would include the Type-A Coronary prone personality. All of these major risk factors should be considered in assessing any individual's risk."

Would you agree with that statement?

A. The only thing that I would disagree with a little bit, as we talked about earlier, was age and sex. Again, I'm not sure I would look upon that as a risk factor as such. Certainly as an association, as we discussed earlier, but otherwise I would pretty much agree.

Q. The definition that I read you earlier,

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I believe, identified risk factor as a factor that does have a statistical association with the occurrence of a disease such as coronary heart disease. In that sense, would you view factors such as age or Type-A personality as being risk factors but perhaps of a lesser magnitude than some of the others that are listed here?

A. Yes.

Q. May I direct your attention to the second column, and it's the second full paragraph, again. If I may read it to you and ask you if you agree with it.

"For a practicing physician, there is little purpose served by trying to rank the major risk factors in order of importance. Rather, it is important to recognize that all of them have a potential role -- " Excuse me. "-- potential major role, and the relative importance of risk factors in individual patients is the practical question of prime importance. Furthermore, a broad knowledge of many risk factors, some less well recognized, may be useful in minimizing

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an individual's risk. For example, dialysis can cause carnitine deficiency, which may, in turn, lead to lipid abnormalities and increased CHD risk."

Would you agree with that?

A. Not quite. And that is that in my experience that if I see a patient who is -- if I had two patients the same otherwise, and, for example, one smoked and one did not, then the smoking, to me, would carry more weight, would make me think more of coronary disease.

Q. So you would personally rank risk factors in individuals' backgrounds in trying to come to some kind of causal conclusion?

A. If I am faced with a patient with chest discomfort, there are some risk factors that I would give more weight to, yes.

Q. Would you always rate smoking as a more significant risk factor than any other risk factor in any other individual's background?

A. The only risk factor that I would probably place equal to that is diabetes.

Q. Doctor, if I came to you and I told you that my maternal and paternal grandparents died of

Page 184 heart attack and that my parents died of heart attacks, and I also told you and reported correctly that I smoked a pack a day of cigarettes for ten years, would you consider cigarette smoking to be the most important risk factor in my background?

A. Again, I don't know the data well enough about the correlation between the amount of smoking and the risk of coronary disease. I think I would -- the other question I would have for you is, is what age were your parents when they had heart attacks?

Q. But assuming that I gave you information that they were all 55 years old when they had their coronaries, would you still rank smoking as the No. 1 risk factor?

A. In that case, if they both had heart attacks at 55, that's a little bit difficult to say because that would qualify as premature coronary disease in both males and females in which case then you would also have to think about is there a congenital hypercholesterolemia present.

Q. So it's fair to say that you wouldn't automatically rank smoking as the number one factor in a person's background without first gathering complete information on other risk factors in the

Page 185 individual's background. 2 A. That's correct. 3 Q. And there may indeed be some patients who have chronic hypercholesterolemia, there may be 4 some patients with chronic hypertension who are relatively light smokers, say, five pack years. And in a case like that, you might place more weight on the high cholesterol and the high blood pressure; is that correct? 10 A. Again, I don't know that data well 11 enough from an epidemiologic point of view to know 12 the correlation. 13 Q. But I am talking about your clinical judgment because you did say that you do place more or less emphasis on certain risk factors in a given 15 16 individual's background? 17 A. In the scenario that you have just painted, I would agree with you.

Q. You would put more emphasis in that 18 19 hypothetical on the high cholesterol levels and high 20 21 blood pressure? 22 A. Probably so. Q. Okay. So it would depend on the individual, if that's the case? 23 24

A. That's correct.

Page 186 Q. You wouldn't make any generalities and say that if someone smokes that that, in your opinion, would always be the most important risk factor in their background, you would have to take each case based on its own facts?

A. That's correct.

Q. Okay.

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MR. ANDRADE: I'll give you another article, and I'd like to have it marked as Defendant's Exhibit No. 7, please.

(Thereupon, the document was marked Defendant Lorillard's Exb. No. 7 for Identification.)

BY MR, ANDRADE:

Q. And this article is entitled, "Mass Intervention versus Screening and Selective Intervention for the Prevention of Coronary Heart Disease," from the medical journal of JAMA.

And I see commentaries, so I don't see the author's name on the first page. Okay, it's

Robert Olson.

If I could direct your attention, please, to the next to the last page, page 2206, the second column and the second full paragraph after the heading "Screening As An Alternative," it

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Page 187 begins, "Consider the unknown factors." Can you 2 find that, Doctor? 3 A. Yes. 4 Q. If I can read it to you, please, and 5 ask if you agree with it. 6 "Consider the unknown factors in 7 CHD. Only 50 percent of the risk of 8 disease can at present be accounted 9 for by the known risk factors. 10 Consider our ignorance of the importance of prostaglandins, 11 12 thromboxanes, prostacyclins, platelet-derived growth factors, the 13 14 'omega-3' polyunsaturated fatty 15 acids from marine fish, procoagulant plasma factors, and a large number of 16 17 additional host and environmental 18 factors. This is a time for more 19 formal and informal investigation by 20 practitioners of medicine." 21 Would you agree with that statement? 22 A. I don't know that. Again, I haven't read the body of the -- of the paper. The only 23 thing that would concern me is the date on this is 1986. And in the last 11 years there have been

Page 188 tremendous advances in the understanding, on a molecular basis, of what happens.

For example, the data that came out about lowering cholesterol has only been out about three or four years, so I really would have to know the whole article and really, in light of the way things are now, I don't know that this is a valid statement.

Q. Would you agree, given current knowledge, that only 50 percent of the risk of coronary heart disease can at present be accounted for known risk factors? And again, now, I'm not reading from the paper. I'm putting that question to you as an independent question.

A. Again, I am not as familiar with the epidemiologic data, so it's a little bit difficult for me to answer that.

Q. So you don't feel as though you can respond to that question?

A. No, I really can't.

Q. You mentioned only two of your patients, or you said extremely rare, to have a patient with coronary heart disease with no known risk factors or risk factors known to you in their backgrounds. Would that be a very small percentage

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of your total patients who have coronary heart disease?

A. Extremely small. Extremely small.

Q. So that would be at variance with at least what Olson reported in 1982, that approximately 50 percent of coronary heart disease cases can be explained by risk factors that were known at that time?

A. But you also have to remember that in 1986 the definition of the normal cholesterol was much higher than it is now. So I don't know if that was included within this data or not. You know, when the NCEP guidelines came out about three or four years ago our definition of what's normal for hypercholesterolemia changed dramatically. So again, I don't know at what level this data was looked at.

Q. Over the years in terms of ability to diagnose cardiovascular diseases --

A. I'm sorry. I was reading a sentence here that was particularly germane.

Q. I'm sorry. I thought you were finished with your response and I was going on with the next question because I finished with that paper a while ago, about three or four questions ago. I'm sorry

Page 190 if you had the misimpression that I was still asking questions on the paper --

A. May I read a sentence?

Q. Well, I think at this point it wouldn't be responsive because there is no question pending.

MR. MIKHAIL: If you need to, complete your answer.

I will insist that he be allowed to complete his answer.

BY MR. ANDRADE:

Q. Well, what question are you -- Okay, Dr. Whittle, you are not allowed to just make statements, so if you can tell me what question you are responding to because I stopped --

A. The question --

Q. If you let me finish, please.

I stopped asking questions on that article about four questions ago.

MR. MIKHAIL: No, you didn't. He was answering the question and he was discussing what we knew about cholesterol levels compared to what we know now.

BY MR. ANDRADE:

Q. That was in response to a question that I put to you that was outside the quote from that

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paper.

A. The last question that you asked me was about would I agree that 50 percent of the risk factors can be accounted for. And what I was commenting on in that response was with this paper being ten years old, not knowing what they included, and then I saw this one sentence that goes on to support that and that's what I'd like to read.

Q. Go ahead.

A. And that is that, "History of heart attack--" let's see, "--diabetes melitis, a serum cholesterol of 350 or a diastolic blood pressure greater than 115 were grounds for elimination."

Now, our definition of what we would eliminate in something like this is dramatically lower, so again, that's why I say that this article may not be particularly pertinent at this day and age.

Q. Doctor, we were talking a few minutes ago about evaluating individuals for risk factors for coronary heart disease. Would you agree that one cannot take a particular risk factor identified in a group of people from an epidemiological study and apply those findings to the individual case

before the practitioner?

A. Could you say that one more time?

Q. Sure. Let me give you an example.

If you have an epidemiological study that reports obese people having a significantly increased risk rate of cardicvascular disease, say coronary heart disease specifically, could you take that finding and apply it to one individual that you were treating that was obese without regard to all other risk factors in his or her background?

Page 192

A. Without regard to other risk factors?

Q. Yes.

A. I would have to evaluate that patient and that would be a factor. If they are obese and there is an increased association, that would, again, make me more suspicious.

Q. Would you agree that if a risk factor, in your opinion, is causally related in populations to the development of cardiovascular disease, that just because an individual has that risk factor doesn't mean that was the cause of their particular case of cardiovascular disease?

A. Depends on which risk factor you are referring to. There are some -- out of this long list that you've given us awhile ago, there are some

	Page 195		Page 196
1	"An extensive body of clinical	1	metabolic problem than a dietary problem.
2	evidence supported by animal,	2	Q. So you would disagree with the Surgeon
3	epidemiologic and metabolic studies has	3	General on this point?
4	established the relationship between	4	A. Yes, I would. But again, though, I
5	high blood cholesterol and CHD risk	5	would disagree with the Surgeon General in 1986.
6	(Grundy 1986). The relationship is	6	Q. This is 1988.
7	strong, continuous and graded."	7	A. 1988. Excuse me. I'm off two years.
8	Would you agree with that statement?	8	Q. Would you still disagree with the
9	A. Yes.	9	Surgeon General on this point today?
10	Q. If I could ask you to turn to pages 91	10	A. Yes.
11	and 92, please. Starting at the very bottom of 91,	11	Q. I'd like to read you another statement,
12	lower right-hand column. I would like to read a	12	Dr. Whittle.
13	statement and ask if you agree with it.	13	"For more than 50 years, research
14	"Although there are many	14	has suggested that diet is a, if not
15	determinates of blood cholesterol	15	the, major environmental cause of
16	levels, no modifiable factor has been	16	coronary atherosclerosis."
17	shown to influence cholesterol and LDL	17	Would you agree with that statement?
18	more profoundly than diet."	18	A. Could you read that one more time,
19	Would you agree with that?	19	please?
20	A. No, I would not.	20	MS. WAGNER: Do we have a copy? Maybe
21	Q. And why not?	21	we can follow along.
21 22	A. The reason is that in many patients	22	MR. ANDRADE: Sure. If I am reading
23	with a dietary intervention you may only be able to	23	from a particular piece of literature in
24	lower their cholesterol 15 percent or so. And so in	24	front of me, I'll be happy to give Dr.
25	a large number of patients there may be more of a	25	Whittle a copy; at other times there are
	*** NTo:	k 20.	·**

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rage 197	1	rage 196
statements I will offer to the Doctor that	1	Surgeon General Koop's program, Shape Up America?
are statements that I would like to know if	2	A. Not really.
he would agree or disagree.	3	Q. So you've not read any materials
BY MR. ANDRADE;	4	related to that?
Q. "For more than 50 years, research has	5	A. No.
suggested that diet is a, if not the, major	6	THE COURT REPORTER: Would this be a
environmental cause of coronary atherosclerosis."	7	good time to change paper?
A. I can't I can agree with it	8	MR, ANDRADE: Yes.
partially but not totally. Because, again, when you	9	(Thereupon, a discussion was held off
are looking at people with elevated cholesterols,	10	the record.)
there are two factors you have to consider: One is	11	(Thereupon, the document was marked
the amount of fat that is ingested, and also how the	12	Defendant Lorillard's Exb. No. 9 for
fat that is ingested is metabolized. So I would	13	Identification.)
so it is a little bit difficult to just make it a	14	BY MR. ANDRADE:
blanket statement. Some people may eat a very low	15	Q. I think I've handed a document to you,
fat diet and still have very elevated cholesterols.	16	Dr. Whittle, that we've marked as Defendant's
Q. Would you agree that diet is a major	17	Exhibit No. 9, and that is entitled "Shape Up
environmental cause of atherosclerosis?	18	America," by Dr. C. Everett Koop.
A. It is a significant cause.	19	Just for clarity, you have not seen
Q. Would you agree that it is a major	20	this document before?
cause? Or in your words would "major" equate to	21	A. That's correct.
"significant"?	22	Q. Nor have you read it before?
A. I would use more significant than	23	A. No.
major.	24	Q. Okay. May I direct your attention to
Q. Doctor, are you familiar with the	25	the it's the second page of the document, the

*** Notes ***

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1	Page 199		Page 200
1	upper left-hand column. And it's in the second	1	BY MR. ANDRADE:
2	paragraph, about halfway through, starting with the	2	Q. Do you consider him a reliable source
3	word "obesity." I'm going to try to point to it on	3	of information on the nation's health? You, Dr.
4	my copy to help serve as a guide.	4	Whittle, would you consider the Surgeon General a
5	A. Did you say obesity?	5	reliable source of information on the nation's
6	Q. Right. I'll let you read that to	6	health?
7	yourself.	7	A. It would depend on what he's talking
8	"Obesity is responsible for more	8	about. He's a pediatric surgeon.
9	than 300,000 premature deaths each year	9	Q. So as a pediatric surgeon do you think
10	in the United States."	10	Dr. Koop is unqualified to give opinions on health
11	Would you agree with that statement?	11	issues?
12	A. I have no knowledge of that. I can't	12	MR. MIKHAIL: Let me make an objection
13	really comment whether it's true or not.	13	here. I want to understand. I think it's
14	Q. Do you consider the Surgeon General to	14	important to understand. Is this an article
15	be a credible source of information on the nation's	15	or a publication as Surgeon General or is
16	health?	16	this simply an article by him as a physician?
17	A. Again, I don't know where his	17	MR. ANDRADE: This is an article by Dr.
18	statistics came from so I don't know if that's	18	Koop. If I can find a given if you look
19	Q. The question is: Do you consider the	19	on the second page, we have marked the date.
20	Surgeon General to be a credible source of	20	So this is authored at a time when Dr. Koop
21 22	information on the nation's health?	21	was not the U.S. Surgeon General.
	A. I would have to know what he's talking	22	THE WITNESS: That's correct.
23	about. I can't think of any reason for him to lie.	23	MR. MIKHAIL: I just wanted to make
24	MR. MIKHAIL: Do you. Do you consider	24	sure I understand. When he was speaking, he
25	him reliable?	25	wasn't speaking as Surgeon General of the

	Page 201
1	United States.
2	THE WITNESS: That's correct,
3	MR. ANDRADE: Just let me ask the
4	question.
3 4 5	BY MR. ANDRADE:
6	Q. Dr. Koop, as the former Surgeon
7	General you recognize him as the former Surgeon
8	General of the United States?
9	A. Yes.
10	Q. Okay. Do you consider Dr. Koop to be a
11	credible source of information about health issues
12	in the United States?
13	A. By and large, yes.
14	Q. Now, do you agree with his statement
15	that obesity is responsible for more than 300,000
16	premature deaths each year in the United States?
17	A. I don't know.
18	Q. Do you have any reason to disagree with
19	Dr. Koop?
20	A. I have no reason to disagree nor do I
21	have any reason to agree.
22	Q. If I could direct your attention to the
23	middle of the second page, Dr. Whittle. After some
24	of those statistics, do you see the portion that
25	starts, "Medical Research"?

A. Yes.

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Q. All right. If I may read it to you. "Medical research has confirmed the startling link between weight and disease. Weight contributes to five of the ten leading causes of death in the U.S. including heart disease, high blood pressure and stroke, diabetes, and some cancers."

Would you agree with that statement? A. It certainly contributes to heart disease, to high blood pressure, stroke and diabetes. Cancer, I don't know.

Q. You have no reason to disagree with that?

A. Nor to agree.

MR. MIKHAIL: As to cancer? As to all of it?

THE WITNESS: As to cancer.

BY MR. ANDRADE:

Q. As to cancer, you are just -- you are just saying that you have no reason to disagree or agree with Dr. Koop regarding that statement as it relates to cancer?

A. That's correct.

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Page 203 (Thereupon, the documents were marked) Defendant Lorillard's Exb. Nos. 10 and 11, 2 respectively, for Identification.) 3 BY MR. ANDRADE: 5 Q. I would hand you another article marked 6 Defendant's Exhibit No. 10, and that's entitled, "Physical Activity and Health, A Report of the Surgeon General, 1996." Have you seen this document 7 8 before, Dr. Whittle? 9 10 A. No, I have not. 10 Q. Could I ask you to turn your attention 11 11 to page 7, please. 12 12 A. Roman numeral or regular page 7? 13 13 Q. I believe it's regular page 7. If you 14 14 15 give me a chance, let me find a better cite. 15 Were you aware, Dr. Whittle, that the 16 16 17 Surgeon General had authored a report on physical 17 exercise and health? 18 18 A. No, sir.
Q. Were you aware that the Surgeon General 19 19 20 20 21 considered regular physical activity to be as 21 important as not smoking in terms of cardiovascular 22 23 disease and risk? I'm not reading from the paper 23 24 yet. 24 A. I am not familiar with that statement. 25

Q. So you were not aware that the Surgeon General viewed physical activity to be a risk factor that was as important as not smoking for coronary heart disease?

MR. MIKHAIL: I object as to the form, if you are actually quoting. Are you actually quoting from the Surgeon General's Report, "as important as"?

MR. ANDRADE: I believe that may be a quote.

MR. MIKHAIL: I think it's just only fair to the witness who is being asked to agree or disagree to say exactly what the Surgeon General said.

MR. ANDRADE: Excuse me. That is not a quote, so let me rephrase that question. I apologize for the confusion.

BY MR. ANDRADE:

Q. Are you aware that the U.S. Surgeon General considered regular physical activity to be as important as smoking cessation insofar as coronary heart disease risk is concerned?

A. I am not familiar with the presence of that statement.

Q. May I turn your attention to page 7,

and it is indeed -- the first chapter on page 7 and if we can just look at the left-hand column, most of the way down, No. 2, if I could read that statement and ask if you agree with it.

"The level of decreased risk of

coronary heart disease attributable to regular physical activity is similar to that of other lifestyle factors such as keeping free from cigarette smoking." Do you agree with that statement?

A. Let me just read this again. Q. Sure. Take your time.

A. The way I read the statement, it doesn't make sense. Oh, okay. I personally disagree.

Q. And why?

A. Because at least in my clinical experience I think that not smoking is much more important, as far as preventing coronary disease, than regular exercise.

Q. Do you think your personal clinical experience would be more definitive on this scientific point than the U.S. Surgeon General's Report?

MR. MIKHAIL: I object to the form.

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THE WITNESS: I also don't know upon what information this is based.

BY MR. ANDRADE;

Q. Your clinical experience would be based upon observations of how many patients, Dr. Whittle?

A. Over the years, I would guess probably 50 or 60,000.

Q. Have you conducted a scientific study of your patient population on the issue of whether or not regular physical activity would have the same effect on coronary heart disease risk as not smoking?

A. No, I have not.

Are you finished with this one?

Q. Yes.

(Thereupon, the document was marked Defendant Lorillard's Exb. No. 12 for Identification.)

BY MR. ANDRADE:

Q. Let me hand you what's been marked as Defendant's Exhibit No. 12. It's an article entitled, "Influences of Cardiorespiratory Fitness and Other Precursors on Cardiovascular Disease and All-Cause Mortality in Men and Women." The first author is Steven N. Blair, and the document appeared

*** Notes ***

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in JAMA.

May I direct your attention to the first page in the section marked "Conclusions," and I'd like to read that to you and ask you if you disagree -- if you would agree with me.

"Low fitness is an important precursor of mortality. The protective effect of fitness held for smokers and nonsmokers, those with and without elevated cholesterol levels or elevated blood pressure, the unhealthy and healthy persons. Moderate fitness seems to protect against the influence of these other predictors on mortality. Physicians should encourage sedentary patients to become physically active and thereby reduce the risk of premature mortality."

Would you agree with that statement?

A. I can't make any comments because I don't know how the study was designed and how it was -- I don't know if their data supports this. I would have to read through the article and see.

Q. Now, are you aware of any studies that would cause you to disagree with the statement?

A. No.

Q. Okay. Thank you. Let me just --Dr. Whittle, Medicaid is a program for the indigent; is that correct?

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A. As far as -- I don't know exactly how it's defined, but basically yes.

Q. That is your understanding?

A. Uh-huh.

Q. Would another word for indigent or another term be low socioeconomic status?

A. I would presume so.

Q. Okay.

Are the heart disease risk profiles -are the heart disease risk factors of lower socioeconomic status individuals the same as those of individuals in the highest socioeconomic strata?

MR. MIKHAIL: Before you answer, I would like to object. I'm not going to interfere, but you have asked a lot of questions over and over and over again. I'm going to be quiet and let you go ahead and ask that and let him answer it.

I really wish we would avoid asking similar questions over and over again. We've done that several times today.

Page 209
With that objection, you may proceed.
BY MR. ANDRADE:
Q. Would you like for me to repeat the
question?
A. Please.

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Q. Are the heart disease risk factor profiles of low socioeconomic status groups the same as those of higher socioeconomic status groups?

A. Do you mean such as the percentage that smoke, the percentage with hypertension? Is that what you are referring to by profiles?

Q. Yes. The heart disease risk factor profiles.

A. I would suspect there may be. There may be some difference. Whether or not that is statistically significant or not, I don't know.

Q. Could you tell me what differences there are between those two groups with respect to heart disease risk factor profiles?

A. I think with regard to an individual patient, there would be little difference as far as if a risk factor was present. I mean, if it's going to be present, it's going to be a factor in either group. But whether or not there may be a different percentage, say, who are hypertensive or a different

Page 210 percentage who smoke, that may be different. And that, I don't know.

Q. Okay. Are you familiar with the

scientific and medical literature reporting that a number of heart disease risk factors cluster, tend to cluster, among low socioeconomic status groups?

A. I'm not familiar with that data.

Q. Is it your clinical experience that that might be the case?

A. I really don't know.

Q. May I ask, do you know if lower levels of education are associated with increases in hypertension and high cholesterol?

A. It would not surprise me, but I don't know that for a fact.

Q. In your opinion, would the clustering of heart disease risk factors among low socioeconomic status groups make it difficult to interpret data on a single risk factor such as cigarette smoking?

A. Again, I don't know that data to know if there is really a statistically significant difference among the different risk factors, so I really -- I would have to look at the information.

Q. Okay.

groups?

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Page 211 You have no knowledge at this point to disagree with the notion that some of these heart 2 3 disease risk factors might cluster among lower 4 socioeconomic status groups? A. I can neither agree nor disagree. 5 Q. You just -- you just have no knowledge? 6 7 A. That's correct. Q. Do you know if people in lower 8 9 socioeconomic groups have different diets than 10 people in high socioeconomic status groups? A. I would think that's certainly a 11 possibility. 12 13 Q. Do you know if they drink more alcohol? A. I cannot address that. I don't know. 14 Q. You just have no knowledge on that? 15 A. No, I don't. 16 17 Q. Do you know if they exercise less as a 18 group, the lower socioeconomic status people 19 compared to higher socioeconomic status? A. I don't know that. 20 21 Q. Is it fair to say as you sit here today, Dr. Whittle, that you just aren't familiar 22 with any differences that might exist in heart 23 24 disease risk factors between lower socioeconomic

status groups and higher socioeconomic status

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don't think that's what he said.
       MR. ANDRADE: Let me rephrase the
    question. I might be able to save us some
    time.
BY MR. ANDRADE:
    Q. Can you identify any heart disease risk
factors that differ among low socioeconomic status
groups as compared to high socioeconomic status
groups?
    A. Are you talking about -- I need to
clarify your question a little bit.
       Are you saying are there some risk
factors that are present in one group that are not
in another? Or are you saying there's a difference
in the relative numbers of risk factors in the
various groups?
       The question almost implied that some
risk factors were effective in lower socioeconomic
groups but not in other groups.
    Q. That's certainly -- well, it's actually
both questions.
       Are you aware of risk factors for
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cardiovascular disease that tend to cluster in low

MR. MIKHAIL: I object to the form. I

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Page 213
socioeconomic status groups in terms of frequency
compared to higher socioeconomic status groups?
MR. MIKHAIL: Objection. Asked and
answered. We went over this area this
morning.
BY MR. ANDRADE:
Q. You can answer, Doctor.
A. Again, as we said just a few minutes
ago when you asked the same question, and that is
that I'm really not aware of that data.
MR. MIKHAIL: I'm not going to do it
now, Tony, but there's going to come a point
where I'm going to instruct him not to answer
if we repeat the same areas on the grounds
MR. ANDRADE: Well, I think these
MR. MIKHAIL: that it's
oppressive
MR. ANDRADE: questions are
MR. MIKHAIL: and annoying to the
witness to have to be repeating the same
MR. ANDRADE: I think the record will
show that these might be in a subject area
that's similar but they are indeed different
questions.
The questions I'm now asking are with

Page 214 respect to differences in risk factors between different socioeconomic groups, and that's not the same as asking if certain risk factors exist.

MR. MIKHAIL: I'm going to work hard to detect those distinctions in order to be fair. But if I think at some point that we are being repetitive, I'm going to instruct him not to answer.

(Thereupon, the document was marked Defendant Lorillard's Exb. No. 13 for Identification.)

BY MR, ANDRADE:

Q. I've handed you what's been marked as Defendant's Exhibit No. 13, Dr. Whittle. Are you familiar with the World Health Organization's Technical Report Series Nc. 841, "Cardiovascular Disease Risk Factors: New Areas of Research"?

A. No, sir, I'm not.

Q. Could I ask you to direct your attention to page 40, please.

A. Okay.

Q. The section 11.3.2 entitled, "Health Related Behaviors." I'd like to read it to you and ask you if you agree with it.

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	Page 215
1	"Health related behaviors may be
2	important in generating social and
3	ethnic differences in health. Numerous
4	studies have shown social class
5	differences in smoking, diet, alcohol
6	intake, physical activity and obesity.
7	These need to be studied wherever
8	socioeconomic and ethnic differences in
9	CVD occur.
10	"The extent" Excuse me. "To
11	the extent that differences in
12	Behaviors do account for social
13	gradients in health, this raises a new
14	set of questions, one step further back
15	in the causal chain. What causes the
16	social gradient in behavior? An
17	analysis of the health risks of smoking
18	will be flawed if it fails to take into
19	account a low social status which in
20	turn is associated with ill health for
21	reasons other than smoking."
22	Would you agree with that statement?
23	A. The I don't know whether I agree or
24	not. And let me just make a point, if I could, in
25	reference to that. I'm not an epidemiologist. And
	*** No
	.10

Page 216 what I am looking at is, a risk factor is a risk factor, regardless of whether you are in a higher or a lower socioeconomic status.

If you are a smoker or if you are a diabetic or if you are hypertensive, it's still a risk factor in either group, and this is really beyond my expertise to be able to comment whether I think this is true or not.

Q. Maybe I can truncate the question by asking, Doctor, in your opinion you are not an expert in what risk factors might cluster in lower socioeconomic status groups as opposed to higher socioeconomic status groups; is that correct?

MR. MIKHAIL: You may answer but I'm going to object as to the form as to whether there even is such an area of expertise. BY MR. ANDRADE:

Q. Do you consider yourself an expert in that area?

Q. And as we sit here today you also can't offer any opinion as to the differences in the magnitude of risk factors for cardiovascular disease in lower socioeconomic groups compared to higher socioeconomic groups?

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Page 217 A. That's correct. 2 MR. MIKHAIL: The court reporter looks 3 like she's ready for a break. 4 MR. ANDRADE: Let me ask --5 MR. MIKHAIL: You want to take five 6 minutes? 7 MR. ANDRADE: Would you like to take a 8 short break? 9 THE WITNESS: Yeah. 10 10 (Thereupon, a recess was taken.) 11 BY MR. ANDRADE: 11 12 Q. Dr. Whittle, if a patient has multiple 12 risk factors in his background for, say, coronary 13 13 14 heart disease, is there any way with scientific 14 15 certainty to identify what the cause was of their 15 16 diseased hearts, assuming they had coronary heart 16 17 disease, a heart attack, using that as an example? 17 18 If one has multiple risk factors in his background, 18 19 19

is there any way of determining with scientific certainty what caused 'hat person's heart attack?

A. No, there would not.

Q. Do nonsmokers develop coronary heart disease?

A. They may.

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Q. And nonsmokers develop the other types

of cardiovascular disease, is that true?

A. That nonsmokers may develop other types of --

Q. Other types of cardiovascular disease?

A. Yes, they may.

Q. You have seen in your practice, say, nonsmokers who have, say, peripheral vascular disease?

Q. Do you know what proportion of coronary heart disease is caused solely by smoking?

A. No, I don't.

Q. Do you know what percentage of peripheral vascular disease would be caused solely by smoking?

A. No, I don't.

Q. And the same question for cerebral vascular disease and stroke, would you know what percentage would be caused solely by smoking?

A. No, I don't.

Q. If a person stops smoking, does their risk for coronary heart disease decline?

A. In my clinical experience, I've seen a number of patients who have stopped smoking but have subsequently had heart attacks.

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Page 219 As far as the percentage or how much it drops or depending on how much they smoked, I cannot answer. But I've seen a lot of patients who had smoked for a number of years but then stopped and who still went on and had heart attacks. Q. All right. Would you attribute the later heart attack to their smoking in those cases? A. If they have been a long-time smoker and they've got more coronary disease, yes, then that may then predispose them to a heart attack. Q. Is there any period of having quit smoking that, in your opinion, would put a former smoker no longer at risk for the development of coronary heart disease? That I cannot answer. Q. Are you familiar at all with the literature on smoking cessation and risk for

coronary heart disease?

A. No, I'm not,

Q. So you couldn't quantify, even on the basis -- well, let me ask you this question: Could you quantify on the basis of your clinical

experiences how much reduced a smoker's risk is if they quit, say, four or five years?

A. I can't -- I can't answer that. I'm

not able to.

Q. Okay. Could you answer that for any

time, Doctor, even ten years?

A. I've not looked at the information that I have nor do I have it available to look and I cannot answer that.

Q. All right. If -- does a smoker's risk also decrease for peripheral vascular disease if they stop smoking?

A. For certain types of peripheral vascular disease, yes.

Q. And what types would they be?

A. Such as Buerger's disease.

Q. Are there types of peripheral vascular disease where if a person stops smoking their risk does not decrease?

A. I cannot answer that.
Q. You have not made a study of your patient population on this particular issue?

A. That's correct.

Q. And can you give me an answer based on your clinical experiences?

A. Not really.

Q. How long would a Buerger's dis -- Let me rephrase the question.

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If a smoker stopped smoking at a particular point in time, how quickly does their risk for Buerger's disease decrease?

A. I cannot answer that. The incidence of Buerger's disease is quite low and I've seen very, very few cases in a number of years, so my clinical experience with Buerger's disease is extremely limited.

Q. Is it an extremely rare disease, Buerger's disease?

A. It has -- again, I've seen very few uses.

Q. Do you know, in the general population, what the incidence would be, one case out of how many thousand population?

A. No, I don't.

Q. Do you know what that would be, Dr. Whittle, for the population of smokers?

A. No.

Q. So it would still be a rare disease even among those who smoke?

A. True Buerger's disease, yes.

Q. Okay. Can you tell me how many cases you have seen in your career?

A. Probably not more than three or four.

Page 222 Q. Do you know if the risk for developing atherosclerosis decreases when one stops smoking?

A. I am not familiar with that data enough to really be able to comment.

Q. Could you offer an opinion based upon your clinical experiences?

A. All I can say is that I have -- I have seen a number of patients who were former smokers even for a number of years who have still had heart attacks. But as far as the numbers or percentages, I can't answer that.

Q. Okay. In your opinion, does smoking cessation decrease the development of atherosclerosis?

A. I can't say that.

Q. You don't know? Are there any --

A. I --

Q. Excuse me. I'll let you finish your answer,

A. I can't say that because once the groundwork has been laid for the development of eventually a heart attack with more plaque being built up, then with that substrate being there, then you may go ahead and progress to a heart attack. But what the cessation — what role that would have,

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Page 223 I can't really address.

Q. So you can't offer an opinion as to whether or not smoking cessation would improve one's outlook in terms of the development of atherosclerosis?

A. Again, I've seen people who have stopped smoking who still progressed on to have heart attacks. But whether or not there is a point after which you have stopped that that would be significant, I cannot answer.

Q. Doctor, I'm not asking about the heart attack, you know, as the final manifestation. I was really asking about the development of atherosclerosis — if I can use lay terms — just the general process of building up plaque inside the arteries and narrowing the opening of the artery. So not necessarily heart disease as an end point.

Do you -- do you have any opinion based upon your clinical experience whether or not if you stopped smoking cigarettes, okay, your prognosis is much better in terms of not continuing to develop atherosclerotic changes?

A. I know data that if you have a problem and you stop, there may be a decreased incidence. But as far as if you stop before there is a problem

Page 224 and then there's a decrease in incidence, that's information I do not have.

Q. Okay. Is that because it's not ascertainable since it's difficult to determine the degree of atherosclerosis at any point in time in a person who hasn't had a heart attack?

A. I think it would be extremely difficult because you have also still got the problem with people that have silent coronary disease, so you don't know whether they've got a problem or not. So that data, I think, would be almost impossible to obtain.

Q. Is atherosclerosis a condition that one observes in children?

A. Under very rare circumstances, yes.

Q. Is it thought -- when is it thought to develop in life as a process? At what age would you begin to see the first signs of atherosclerosis?

A. You can see some change at a relatively young age, but the problems that may lead to the development of atherosclerosis in children -- there are some very specific things like a progeria, some of the isolated type 2 hyper ipid proteinemias, and things of that nature.

Q. And this would be in very young

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children? Would you define "children" by giving me an age range or an age marker?

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that opinion?

A. No, I cannot.

A. I think in progeria you could probably see children probably in the range of ten or eleven. If you are talking about the type 2 hyperlipid proteinemia, you are probably talking about, I would guess, probably mid to late teens on rare circumstances. Also in the cases, also, some even more rare anomalies like homocystinuria. You may see some changes there. Again, though, those are extremely rare.

Q. Can you have atherosclerosis develop in children?

A. I would think that would be extremely

Q. Have you ever seen it in any of your patients?

A. Again, I don't deal with the pediatric population.

Q. What would be the age cut off? I'm not sure how pediatrics is defined in age range.

A. I really don't see -- I rarely ever see anyone less than 16 years of age.

Q. Okay. I think you mentioned that you could have a heart attack without or you said silent heart disease. Could you explain silent heart disease for me?

A. Silent heart disease is someone, for example, with a heart attack - who has had a heart attack who has never had any clinical manifestations; that is, they have never had chest discomfort, they have never had shortness of breath, but they go in, routine electrocardiogram, they show evidence of prior heart attack.

Q. Is it possible to have a heart attack without atherosclerosis?

A. That would — you can, but that would be extremely rare. It would have to be either on a traumatic basis or on an embolic basis, and those things would be exceptionally rare.

Q. Can you have coronary arteries that are occluded without having a heart attack?

Q. Can you have arteries in the more peripheral locations and have disease of the extremities without having the arteries and the peripheries occluded?

If I can restate the question, that was terribly confusing.

Can you have peripheral vascular

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Page 227 disease without peripheral blood vessels being 2 occluded? 3 A. Peripheral vascular disease does mean -- peripheral vascular does mean peripheral 4 5 vessels are occluded. Q. Could you have a vasospasm in a 7 peripheral blood vessel that isn't occluded through atherosclerosis? Could that lead to a diagnosable 8 9 disease? 10 A. Yes. But that's extremely rare. 11 Q. But it can happen? 12 A. Extremely rarely. 13 Q. Doctor, in your opinion is hypertension 14 the number one risk factor for stroke? 15 A. Again, you would have to separate out whether you are talking about hemorrhagic stroke or thrombotic stroke. In hemorrhagic stroke, it would 16 17 18 be a very strong risk factor; in thrombotic stroke 19 it would not be. 20 Q. Is hemorrhagic stroke associated with 21 cigarette smoking? A. To my knowledge, yes. 22

Q. Could you cite any study to support

Q. Is this based on your clinical experiences?

A. Clinical experience, some textbooks in the past. But again, I cannot specifically tell you where.

Q. All right. Have you seen hemorrhagic stroke in patients who don't smoke?

A. Yes.

Q. Is it more common in patients who don't smoke?

A. I can't say that.

Q. You have no --

A. Again, I have not --

Q. You've not done a study?

A. I've not looked at our data in any routine fashion.

Q. Can I ask you, do you keep any data in an organized fashion with respect to smoking and cardiovascular disease based upon your patient population in your private practice?

A. No, sir, because there is no reason for

22 me to.

23 Q. You have never done any kind of formal 24 25

A. No, sir. I'm in practice; not in an

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academic setting.

Q. All right. So in your observations, I think as you have made clear, are then basically -- your clinical -- you compile those experiences to offer your opinions; is that correct?

A. That's correct.

Q. All right.

The second type of stroke, I believe you mentioned, is thrombotic?

A. Yes.

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Q. And do you see thrombotic stroke occur in nonsmokers?

A. Yes.

Q. Doctor, what criteria would you use in evaluating a patient who had multiple risk factors for coronary heart disease in determining what the cause was of their coronary heart disease?

A. Could you restate that, please?

Q. Yes. Perhaps it might be clearer if I

used an example.

You have a hypothetical patient, and say the hypothetical patient has five risk factors for coronary heart disease: They're a smoker, they have a family history, they have hypertension, they have high cholesterol, and they have diabetes. What criteria would you use to evaluate what the cause was of the coronary heart disease in that particular patient?

MR. MIKHAIL: I want to object as to the form in that you are restating what the major factors that Dr. Whittle stated earlier because I don't believe they included family history as one of the ones that he included. But since it's a hypothetical question, that's fine.

MR. ANDRADE: Just to try to address the objection, I'm not suggesting that these are your factors. It's purely hypothetical. BY MR. ANDRADE:

Q. I'm saying a patient comes to you and they have those five risk factors. They have high blood pressure, high cholesterol, they have a family history, they smoke, and they have diabetes. And you evaluate that patient and they have coronary heart disease, say they've had a heart attack.

What criteria would you use to try to determine what the biological cause was of the heart attack in that patient?

A. I would use no criteria.

Q. You would use no criteria whatsoever?

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A. Exactly. And the reason I say that is the following: If a person has had a heart attack, we need to modify every risk factor that we can to prevent a second heart attack. So I'm not going to tell a person who was a smoker, quit smoking but let's not control your diabetes. Or let's control your diabetes but you continue to smoke because we have to modify all risk factors that we can.

Q. Okay, but that really wasn't the

question, Doctor.

I understand what you are saying, that for prognostic purposes for future risk you would advise that patient to reduce all those risk factors that they could, correct?

A. That's correct.

Q. But with respect to the first heart attack, what criteria would you use in determining what caused that first heart attack?

A. I can't.

Q. And why is that?

A. Because if you have multiple risk factors, I cannot tell you did one risk factor aggravate another? Or are they all working in combination? Did one do it and not the others? And I cann't separate that out.

Q. Is there no test or procedure you could perform to get the answers to that question, to determine what the cause was of the heart attack?

A. No.

Q. Is there any kind of chemical analysis you could perform on the diseased heart to try to answer what caused it specifically?

A. No.

Q. So there would be no marker in the heart tissue that would tell you if it was diabetes or if it was high cholesterol or that it was smoking specifically that caused that?

A. No.

Q. Is it fair to say that medical science simply doesn't have those kinds of tests available to make those determinations?

A. That's correct.

Q. If we had --

A. That's in the case of multiple risk factors.

Q. Sure.

If we had a patient who came to you and also had multiple risk factors for peripheral vascular disease, what criteria would you use in trying to determine which of those risk factors

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caused the peripheral vascular disease in that patient?

A. Again, I can't tell you which ones specifically did in the multiple risk factor. That's impossible.

Q. Is it for the same reason? Is there any kind of diagnostic test or laboratory test or procedure that would allow you to ascertain the cause of the peripheral vascular disease in that

A. Not in that specific case, no.

Q. Could you obtain the material that caused the atherosclerosis in the peripheral vessel and do any kind of analysis on that that would help identify the cause?

A. No.

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Q. Is there any kind of gross observation that a pathologist could make on the diseased artery in the periphery -- excuse me -- the diseased blood vessel in the periphery, and could the pathologist, by some type of gross or microscopic evaluation, tell us what risk factor caused the disease in the peripheral vascular case?

A. You can't do that because atherosclerosis is the end product. And how you got there, you cannot ascertain.

 Atherosclerosis is a nonspecific, not-tied-to-one-risk-factor type process?

A. It may be tied to one risk factor if no other risk factors are present.

Q. But in a person --

 A. In a case of multiple risk factors, that's difficult. Did one accelerate, did smoking accelerate the effect of hypercholesterolemia? Did smoking accelerate the effect of the hypertension? You can't say.

Q. All right. And you couldn't tell, on the other hand, if smoking played no role, I suppose, if there's no test that would give you a marker for smoking or a marker for cholesterol or a marker for high blood pressure?

A. We can't prove it one way or the other.

Q. There's just no scientific, medical or diagnostic test that you know of that could give us the answer to that question?

A. There is no pathologic change that would be specific for one particular risk factor over another because, again, we're looking at the end product.

Q. Okay. And that would be true -- I'm

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Page 235 trying to think of the categories that you talked about this morning. Coronary heart disease was one, peripheral vascular disease was the other, and then we used cardiovascular disease as a general term,

> MR. MIKHAIL: Cerebrovascular disease. MR. ANDRADE: Thank you.

BY MR. ANDRADE:

Q. Cerebrovascular disease, the same question. Is there any way if we have a cerebral vascular accident, if one can take the material from the brain and identify through any kind of biological test, laboratory test, what the cause was of that?

A. I wish it was that simple.

Q. And is it for the same reason, is that secondary to atherosclerotic build up in the arteries that lead to the brain?

A. In the case of a thrombotic or embolic stroke, yes; not in the case of hemorrhagic stroke.

Q. That's right. You distinguished from the two. But in either case is there any, I guess, laboratory test or diagnostic test that can be performed when you have a patient with multiple risk factors to identify which risk factor, if any,

caused the atherosclerotic build up?

A. Not in the case of multiple risk factors.

Q. Okay. And therefore we also couldn't look at the thrombus or hemorrhaging of the brain and determine what specifically caused it biologically?

A. You can't do that.

Q. Is there any way a pathologist could microscopically look at the arteries leading to the brain and be able to give his medical opinion as to what caused -- in the presence of multiple risk factors -- what caused the atherosclerosis?

A. That would be impossible.

Q. Is there anything he could do to section the tissue, to section the diseased arteries leading to the brain and come up with a microscopic analysis of what caused that build up?

A. No. Again, because you are looking at the end point, so you can't differentiate in multiple risk factors.

Q. Could a pathologist, if he had a heart from a patient who suffered a heart attack -- and again, this patient having multiple risk factors -could a pathologist take tissue sections from that

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Page 237 heart and look at them under the microscope and tell us what was responsible for the heart attack, what risk factor?

A. No.

Q. If we had a patient with peripheral vascular disease and do those diseases sometimes require removal of tissue or amputation?

A. Yes. Q. Okay.

Q. Okay.

If we had that surgical specimen, could a pathologist do some sections on the diseased extremity that had to be removed and put under the microscope and diagnose what the cause was of that disease?

A. No.

Q. Radiologically is there any way of making that determination in terms of causation of peripheral vascular disease?

A. No. Again, because you are looking at the final stage of atherosclerosis and you really

can't differentiate at that time.

Q. So the radiological techniques would just tell you that you have the precursor, say the atherosclerotic build up, but it couldn't tell you what caused it?

A. That's correct.

Q. Okay.

Now, I wanted to ask you a few questions about self-reporting. Not in the context of cigarette smoking or diet which we did touch on earlier, but just more general questions.

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If a doctor comes to you -- if a patient comes to you -- I'm sure you have patients who are physicians as well -- but if a patient comes to you and they say to you, "Doctor--" and it's the first visit. "-I have angina," would you accept the self-reporting or would you ask the patient some questions to determine if they're correct in giving you what they believe to be their medical history?

A. I would certainly ask that and confirm

Q. Would you confirm it by asking questions about where the pain is or how frequent the pain is? What kinds of information would you ask of me?

A. I would ask, Is it exercise induced? How long does it last? Is it associated with shortness of breath? How long does it last? Questions of this nature to help me differentiate which it is.

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Page 239 Q. Okay.

In your opinion or -- excuse me -- in your experience have you had patients who would come in and, as a lay person, tell you that they believe they had a certain condition, but upon probing by you and gathering of information by you, you determined that the diagnosis was not correct?

A. Yes.

Q. All right.

If I came in to you, moved here from, say, some other state and said, "Doctor, I had a heart attack five years ago," would you accept that self-reporting or would you ask me some questions to try to determine if I really did have a heart attack five years ago?

A. I would try and ascertain whether or not you, in fact, did.

Q. And would you ask me to provide medical records from my previous treating cardiologist?

A. Yes, I would, if that were appropriate.

Q. Do you do that on occasion?

A. Yes.

Q. Would you also do that for peripheral vascular disease, cerebrovascular disease? If people claim to have those conditions in the past,

Page 240 would you ask them if they could provide medical records?

A. Yes, I would.

Q. And what kinds of questions would you ask me about my heart attack if I came to you and said, Doctor -- it's my first visit. I had a heart attack five years ago now I'm having some pain in my chest and I'm worried? What would you ask me to try to determine if my self-reporting was correct?

A. Is self-reporting about the pain or about the heart attack?

Q. About both. About the heart attack, about the heart attack.

A. I think about the heart attack I would want to know how long you were in the hospital, did you have an angiogram, did they tell you how much damage there was, was an echo done that showed any damage, and things of that nature.

Q. All right. If I'm not terribly sophisticated and I can't remember the names of the tests, would you repeat some of those tests?

A. Only if it were necessary.

Q. That would depend on a case-by-case basis?

A. Exactly.

Page 241 Q. All right. But if you suspected some of my information -- if I would tell you to the best of my ability in all honesty what I recall, there might be cases where you would still repeat certain 6

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Q. Is that because you had found, in your clinical experience, that often lay people do not accurately report what they think they had in the way of diseases or conditions in the past?

 A. I think it's not unusual, particularly when you are dealing with the heart. Some people may say, Well, I've had 15 heart attacks and that's just not going to happen. And so in that situation what you may actually find is the patient may have been admitted 15 times but there was no damage. So you just have to go to a further end to substantiate whether or not it was really true or not.

Q. If the patient comes who has had 15 heart attacks, you would probably tell him he was pretty lucky?

A. I guess. I would check it out, first.

Yeah.

Do you often find, in your clinical experience, that a patient will report not 15 but

Page 242 had a heart attack or some condition and when you investigated actually was a different -- the

diagnosis was incorrect that they were

self-describing?

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A. That's not uncommon for that to happen.

Q. It could be -- what are some of the differential or what were some of the other problems that they actually could have been experiencing when they thought they had had a heart attack?

 They could have had some esophageal reflux, it could have been pericarditis, musculoskeletal pain. It could have been a lot of different things.

Q. Okay. If someone complains of poor circulation to their feet or hands and they say, I've been diagnosed as having peripheral vascular disease, would you ask me questions to determine if my self-reporting was accurate?

Yes, I would.

Q. And what kinds of questions would you put to me?

 A. I would ask you, Do your legs or buttocks cramp when you walk? Does it stop when you go away? Then I would need to substantiate that with a physical examination as well.

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Q. Would there be any tests you might run to try to get a definitive diagnosis in that case? A. If a person is significantly limited and the physical examination tended to support that, I might do some Doppler studies of the lower

extremities to see if there was any decreased blood

flow. Q. Doctor, I wanted to ask you a few specific questions about your expert statement. I think we had that marked early on.

MR. MIKHAIL: I think it was 2.

MR. ANDRADE: Yeah. Let me see if it's on this stack.

BY MR. ANDRADE:

Q. Let me give you Defendant's Exhibit No. 2 which is your expert disclosure statement in this

Now, in the second sentence, Doctor,

let me read it: "Dr. Whittle is expected to

testify that smoking causes and contributes to heart disease including coronary heart disease, cardiovascular disease, atherosclerotic peripheral

vascular disease and aortic aneurysms."

Page 244 Can I ask what distinction you make between a cause and something that contributes to a disease? I'm not asking in heart disease necessarily, but just the general question: How would you differentiate a cause from something that contributes to a disease?

MR. MIKHAIL: Objection. Asked and answered. We went over that this morning.

You can try again.

THE WITNESS: I would probably have just left it as causes.

BY MR. ANDRADE:

Q. I believe we talked about risk factors this morning. I don't think I asked you this question, but that's fine.

You probably would eliminate the word "contributes"? Is that your testimony?

A. I probably would.

Q. All right. So you would amend your testimony to say, Dr. Whittle is expected to testify that smoking causes heart disease, so on and so

A. (Affirmative.)

Q. Again, I'd like to ask you what your criteria are for determining -- making a

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determination, offering an expert opinion that smoking causes coronary heart disease.

A. I think we've gone over this earlier, but basically, as I said earlier, I said in medicine I don't think we use the word "cause" very often.

I think when we are dealing more with infectious diseases, we will use the word cause. For example, the bacillus for diphtheria causes diphtheria.

But when we are dealing with coronary disease, I think we all feel very comfortable saying certain things may cause the coronary disease, but we cannot fully explain the basis on down to a molecular level. So I think that's why we probably don't use the word cause but we use the word risk factor. But we're still implying cause, but that's just trying to be reasonably scientific about that is why we probably don't use the word cause very often.

Q. Okay. Do you use the word cause because if you told your patients smoking is a risk factor for disease it might not have the same impact on them as if you looked them in the eye and said, Smoking can cause heart disease?

A. I think we tell patients that but I

don't think that's the specific reason.

Q. I know I've asked the question before, but I'm not sure that you've responded to it. Could you explain for me, in the context of your expert opinion, how you are differentiating your use of the word cause from risk factor because I think what I'm hearing is you might use them interchangeably.

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A. And that's what I said earlier.

Q. Okay. So in your opinion the way you use — in your opinion there is no difference in the meaning of the word — term "risk factor" and the word "cause"?

A. Yes. And that's also consistent with what I said earlier and that's why I don't like to use the terms as age and sex cause coronary disease or as a risk factor because I use the terms more interchangeably. And I can't say that age or sex causes coronary disease. And so I tend to use the terms more interchangeably and that's why I don't like to consider those necessarily as risk factors.

Q. Anything that you identify as a risk factor you would also identify as a cause; is that correct?

A. That's correct.

Q. All right.

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Could you give me the specific bases of your opinion in this case that cigarette smoking causes coronary heart disease?

A. I have to do that based upon my clinical experience.

Q. Okay.

A. In my clinical experiences over the years I have seen hundreds and hundreds and perhaps even thousands of patients who have been smokers but who are not hypercholesterolemic, who are not diabetic, who that is their only risk factor for coronary disease and who have developed very extensive coronary atherosclerosis.

Q. All right. But -- so you are saying in some of your cases you have determined cigarette smoking is a cause of disease because it is the risk factor-- Or the factor. I'll try not to use "risk factor" to avoid confusion. -- is the factor that is present that in your opinion would explain the development of disease?

A. I would not use the term "some," but it would be a great number of patients on whom that is the only risk factor.

Q. Okay. Is it your testimony that cigarette smoking causes heart disease in all

smokers?

A. No. What I'm saying is I see a large number of people who are smokers with coronary disease because, again, I'm seeing when they develop coronary disease that I see a large number of these patients, that's the only risk factors. And my feeling is that that is what is responsible for the coronary disease.

Q. In those cases do you take a thorough medical history to try to determine if there are other risk factors present in the individual's background?

A. Yes, I do.

Q. Okay. But you do have a certain number of patients where smoking is the only risk factor in their background?

A. A large number.

Q. A large number, okay. And you have not been able to identify literally, in those cases, any other risk factors in their background for coronary heart disease?

A. That's correct.

Q. Can you give me a percentage of your patients who have heart disease where, you know, smoking is the only risk factor in the background?

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A. First of all, you have to say coronary heart disease. It's not heart disease.

Q. Excuse me. Coronary heart disease. Let's stick with coronary heart disease.

A. I have not looked at that data and it would purely be a guess.

Q. Could you give me an estimate? Your testimony is based on your clinical experience so it is difficult for me to get an appreciation for how common an experience this is unless you make an attempt to estimate it for me.

A. I would guess -- and again, purely accept it as that, that smoking is present in the people with coronary disease probably in excess of 90 percent of the time. As that being the only risk factor, I would guess in the range of 40 to 50 percent of the time.

Q. All right.

Would you agree, Dr. Whittle, that your patient population here in this area wouldn't necessarily be representative of the patient populations that other physicians have in the other parts of the State of Florida?

MR. MIKHAIL: (object to the form. MR. ANDRADE. Let me rephrase that,

please.
BY MR. ANDRADE:

Q. Is your patient population in your group private practice representative of the patient populations of other cardiologists in the State of Florida?

A. I believe it is.

Q. And you would say that even though you are fortunate to live in a relatively affluent area of Florida?

A. Yes. I've talked with other cardiologists in linking our data with -- or our assessments with other patients or with other practices, and the -- the results and the feelings are almost identical to other people. So I don't think we have a skewed population at all.

Q. Have you done any -- any studies on your population comparing them to the patient populations of other cardiologists in the State of Florida?

20 Florida? 21 A.

A. No, because there is no reason to.

Q. Is this area a favorite retirement community? Is it — do you have a lot of retirees in this area?

A. Yes.

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Q. Okay. Do you think that other cardiologists throughout the State of Florida would have a similar proportion of retirees in their patient populations?

A. Probably depends on the section. Probably maybe a little bit less so in northern Florida.

Q. And I think, though, you did testify that, again, this area enjoys a high standard of living, has a lot of affluent individuals, and so you have a significant percentage of affluent individuals in your particular practice?

A. Yes.

Q. Do you think that other cardiologists in the State of Florida would have the same percentage of affluent individuals in their practices?

A. I've never looked at that. I think our -- our impression is that clinically we're seeing the same thing. But as far as the socioeconomic that's -- I don't know that we have ever really even discussed that.

Q. All right. So there might be some differences between the demographics of your particular practice and the demographics of the practices of other cardiologists in the State of Florida?

A. For the demographics in the patients, yeah. But I think as far as the disease process, no.

Q. Okay. Now, I'm not asking about, you know, whether you would see the same percentage of heart attacks or strokes, say, as other cardiologists. But the demographics of your patients, if you would have a different patient mix, if you will, than other cardiologists in other parts of Florida?

A. I don't think we would because, again, we're seeing these patients once they come in with a problem. And that's going to be fairly universal.

Q. So you think that your particular patient population is representative of the patient populations of other cardiologists in the State of Florida?

A. I think by and large, with some exceptions.

Q. Okay. I wanted to ask you again about your opinion that cigarette smoking causes -- and then the next item you have is cardiovascular disease in your report.

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A. Yep. Q. But I think we agreed earlier that cardiovascular disease is a broader term.

A. That's correct.

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Q. So you are not saying that cardiovascular disease is a separate clinical entity but it's more of an umbrella term that would encompass coronary heart disease, atherosclerotic peripheral vascular disease and aortic aneurysms; is that fair?

A. That's correct.

Q. I didn't want to waste time on that if we could agree --

A. We've beaten that enough.

Q. – that it wasn't a separate disease

Okay, then let me ask the question: What is the -- it is your opinion that cigarette smoking causes atherosclerotic peripheral vascular disease; is that correct?

A. That's correct.

Q. Could you tell me the bases for that opinion? I would like to have all the specific bases of your opinion.

A. I think, again, based upon my clinical

experience -- I think I can probably only recall very few patients who have developed significant 2 3 peripheral vascular disease who did not smoke. Extremely few. I don't think I've ever seen a person with an aortic aneurysm who did not smoke. 5

Q. All right. I would take it that you took thorough medical histories on those individuals to try to ascertain any other risk factors in their backgrounds for peripheral vascular disease; would that be correct?

A. We do the same thorough examination and

questioning on everybody.

Q. Is -- in your experience have you found that there is a certain percentage of people in your practice and your experience that have atherosclerotic peripheral vascular disease where smoking is the only identifiable risk factor in their background?

A. I would say probably more so in peripheral vascular disease than in coronary heart

Q. Could you give me, again, an estimate, a percentage estimate? A. Again, I think as an example with

aortic aneurysms, I don't think I've seen anyone

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that did not smoke. As far as if what you are

getting at, those people who smoked only, I would think if we're seeing maybe 40 to 50 percent of people with coronary disease in whom that was their

only risk factor, my guess - and again it's only that -- that in peripheral vascular disease I bet we're looking more at 80 -- probably 70 to 80

Q. Okay. Again, trying to take them one entity at a time, that way we'll be able to do it more orderly, so for atherosclerotic peripheral vascular disease patients, patients that you have with that problem, peripheral vascular disease, approximately what percentage would have smoking as the sole risk factor in their background?

A. I would -- I would guess easily 70 to

Q. 70 to 80 percent, okay. But you do, on occasion, have patients with atherosclerotic peripheral vascular disease that don't have smoking in their backgrounds?

A. It would be rarer than hen's teeth.

Q. In your experience virtually every patient with peripheral vascular disease is a smoker?

Not everybody, but almost.

Q. Virtually. No, I said virtually all.

A. Virtually all.

Q. Could you put a percentage on that for me, please?

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A. I would say certainly in excess of 95 percent.

Q. And 70 to 80 percent of those, just so I understand, would have cigarette smoking as the sole risk factor in their background for atherosclerotic peripheral vascular disease?

A. That's correct.

Q. Okay. And finally, aortic ancurysms?

A. Aortic aneurysms are a little bit different from our clinical experience primarily because we see very few of those primarily. Most of the aortic ancurysm are seen primarily by the vascular surgeons.

Q. Under what conditions would you see patients with aortic ancurysms? Would you be the diagnosing physician in those cases?

A. Yes. It would be someone who we are seeing for other reasons, and in the process of examining the abdomen felt an ancurysm and evaluated

Page 257 Q. I take it that your opinion is that smoking causes aortic aneurysms? A. Yes. Q. All right. And could you again identify all of the specific bases of that opinion A. Again, it would be based upon my clinical experience. And I don't believe I've ever seen an aortic aneurysm in someone that did not Q. What percentage of the aortic aneurysms that you have seen in your practice would you say had eigarette smoking as the sole risk factors in the patient's background? A. I would, again, put it roughly the same as I did for the peripheral vascular disease. Q. And that would be greater than 95 percent? Oh, excuse me. Wrong question. That would be 70 to 80 percent? A. Yes. Q. All right. So let me restate the question. I think I may have mixed up my figures.

Is it true that in your clinical

experience in 75 to 80 percent of patients who have

aortic aneurysms, cigarette smoking is the sole risk

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factor in their background?

A. At least that much.

Q. At least that much. A. Perhaps even higher. But again, I'm having just to estimate what that would be.

Q. And is it also correct that in your personal clinical experience that 95 percent of all patients with aortic aneurysms have a history of smoking?

That much or more.

 Q. Would that be any history of smoking, Dr. Whittle? In other words, would that include people who smoked half a pack a day for five years as well as people that smoked three packs a day for 30 years?

A. Again, I have not quantitated this, but my feeling is that it is someone who has smoked significantly. And again, I would have difficulty defining that exactly, but someone who has smoked a significant amount for a significant length of time.

Q. Just so I understand, then, when you give me these figures for coronary heart disease, peripheral vascular disease and aortic aneurysms, when you say they had smoking as a sole risk factor in their background or smoking as a risk factor in

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Page 259 their background, that's without regard to amounts 2 smoked? 3 A. That's correct, because I have not quantitated that. 5 Q. And that's without regard to duration 6 of smoking, how many years the patient may have 7 smoked? 8 A. That's correct. Q. You just simply haven't made a study of 9 10 this in your patient population? 11 A. Yes, because there was no reason for me 12 to. 13 Q. Okay. No reason because, as far as you 14 are concerned, if there was smoking in the 15 background that was enough for you to base a 16 finding or a conclusion of causation? 17 Q. I know we talked a lot of epidemiology 18 but let me ask the question. Are you familiar with 19 20 epidemiology that discusses the risk for coronary 21 heart disease, peripheral vascular disease and aortic aneurysm as a function of amount smoked? 22 A. It would not -- I am not specifically 23 familiar with it, no. 24 25 Q. No.

Page 260 And are you familiar with the literature that also looks at those three disease entities and the risk of developing those diseases as a function of duration of smoking, that is, the number of years that one has smoked?

A. Again, I'm not intimately familiar with that data.

Q. Would it change your opinion if there are data that show that the -- that there is little or no increase in risk for, say, coronary heart disease among people who are light smokers?

A. I would just have to look at the data

and see how it is collected.

Q. It might have an impact on your opinion?

A. Again, as I mentioned earlier today, if it's good science, I would accept it.

Q. So if -- perhaps if it's science funded by the National Institutes of Health, the National Cancer Institute, that is science you might consider to be good quality science?

MR. MIKHAIL: I object to the form but you can answer it.

THE WITNESS: If it's in the American Tobacco Institute, if it's good science, it's

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good science.

BY MR. ANDRADE:
Q. You don't -- you don't personally
believe that whoever supports the work necessarily

guarantees that it's good science; you will evaluate it in its own individual scientific merit --

A. That's correct.

Q. -- any studies of this nature that might be presented to you?

A. That's correct.

Q. Would it be of interest to you to have available in the formation of your opinions information concerning the risks of cardiovascular disease including coronary heart disease, peripheral vascular disease, and aortic aneurysms that addressed the relative risk of developing those diseases as a function of smoking cessation? And that is, what the risk is after a people have quit smoking for certain periods of time?

A. I would certainly be willing to look at

the data.

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Q. All right. I don't want to get into a lot of unnecessary areas and so I just want to ask one question. Basically your expert opinions in this case are predominantly based on your own personal clinical experience in your medical practice?

A. Yes, it is.

Q. And is it fair to say that the only exception to that, you know, would be if some of the articles that we have discussed today that you generally recall reviewing with the 1983 Surgeon General's Report but don't necessarily come to mind today during our deposition?

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A. That's correct.

MR. ANDRADE: Mr. Mikhail, I don't want to mischaracterize our earlier discussion. Did you say that if you provided any information for Dr. Whittle to review prior to trial that you would make that available to us?

MR. MIKHAIL: Absolutely. We don't anticipate that we would, but in the event that we do --

MR. ANDRADE: I understand. Would you also be amenable to allowing us to question Dr. Whittle further on any additional materials you might provide?

MR. MIKHAIL: If there is any additional material that we give him to

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review that he indicates he's going to rely upon in his testimony, we will certainly give you an opportunity to redepose him only for the limited purpose of asking him about those documents

But I will say, so the record will be absolutely clear, we will not offer him voluntarily for redeposition for you to depose him on just anything that we provide him if he doesn't rely on it. And the reason I say that is so you will understand neither Ms. Wagner nor I neither Dr. Whittle know why that cartoon candy article was furnished to him by someone on our side, and he obviously didn't rely on it. He said he didn't rely on it.

If something like that were to happen, a paralegal in the firm is instructed by someone to send it to everybody, I don't want you to have a chance to redepose him because of that. If he relies on it, certainly.

BY MR. ANDRADE:

Q. You are not going to be relying on that document at all —

A. No.

Q. -- for any of your opinions? I think you testified you haven't.

A. That's correct.

MR. MIKHAIL: I just don't want every time somebody mails something to him that warrants re-deposition.

MR. ANDRADE: I understand. MR. MIKHAIL: Is that good? THE WITNESS: That's good. MR. MIKHAIL: Okay.

BY MR. ANDRADE;

Q. Doctor, are clinical observations based on one's individual practice, when you view that data, to be of the same scientific value as carefully designed and controlled epidemiological studies?

A. I think if I'm dealing with a patient in the middle of the night and there's a real problem, the information that I have available to me from a clinical experience is incredibly worthwhile. There may be some few articles and things that may make such a difference, you know, with what I'm going to do that may be particularly important. But I think I probably rely on my clinical experience probably more so than anything.

Q. Would you agree that one's clinical experience is not the same as a controlled scientific study?

A. That's correct.

Q. You -- you accumulate your experience in dealing with a number of patients but you don't go back and pull from the records, for instance, for every patient that you have seen with coronary heart disease information about smoking history, diet, exercise level, diabetes, so on and so forth? You haven't done that, you haven't collated that information?

A. No. But I might also say that quite the opposite is also the case, and that is that many times those of us with a large clinical experience have had ideas and thoughts that we have not had the time to pursue which years later turned out to be the case.

So that's not to downgrade the importance of the clinical experience because, again, if we had the time and the means, we could probably do the same thing. But I think many of us with a great deal of experience have been led to the same conclusion of some long studies before the studies were even done or conceived of.

Q. You have not applied any statistical analyses to your clinical observations?

A. No.

Q. The percentages you offered today are your best estimates based on your experience?

A. That's exactly right.

Q. Okay. But in the sense of biostatistics or epidemiology, you haven't done any statistical analysis using formal statistical tests?

A. That's correct.

Q. Okay. When you accumulate your clinical experience based on viewing patient after patient after patient, have you attempted to, in some way, control, you know, for different variables that you would consider to be potential causes for cardiovascular disease?

A. No, because that's impossible for me to do.

Q. That just isn't possible in the context of a clinical practice?

A. Not with what I do.

Q. All right. Are you familiar at all, Dr. Whittle, with any of the animal inhalation experiments that have exposed animals in laboratories to tobacco smoke?

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A. No, I'm not.
Q. Okay. You have no knowledge of those whatsoever?

A. No.

Q. Do you have any knowledge of a large scale inhalation study funded by the American Cancer Institute that occurred sometime in the late seventies, early eighties?

A. No, I'm not.

Q. Not aware of that at all?

A. No.

Q. Okay. Would you consider animal inhalation experiments, where animals were exposed to tobacco smoke but were fed the same diet or handled in the same manner who were put under the same degree of stress, you know, were monitored to ensure relatively the same levels of cholesterol, so on and so forth, where other risk factors were controlled for, would you view those to be -- the results of those to be important information to someone who is making causal judgments about smoking and heart disease?

A. I don't know if I would or not because it depends upon which animal is being used, and is that animal one to develop atherosclerosis. For

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example, you can feed a rabbit a high
atherosclerotic diet and they will develop blood
vessel occlusions; however, histologically it's not
precisely the same as what you see in humans. So I
don't know if that data can be extrapolated
necessarily.

Q. Okay. Assuming that the scientists

have thought about that problem and have selected a model that can develop human-type atherosclerosis. Assuming that fact or, excuse me, assuming that, would the results of those experiments be of interest to you in formulating any of your opinions?

A. It would be such a tremendous leap of faith, I don't know if you can make that.

Q. Because you think that the results of animal experiments aren't extrapolable (sic) to the human population?

A. Some are clearly not.

Q. Would you say that all animal experiments aren't extrapolable or cannot be extrapolated to the human population?

A. No, I can't say that. I don't know if

it can be extrapolated or not.

Q. Certainly our regulatory agencies, such as the Food and Drug Administration, rely on animal

data, don't they?

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Q. So would you agree that animal data and properly designed, properly conducted animal studies would have some relevance to the human situation in terms of whether smoking causes cardiovascular disease in humans?

A. I don't know if that's the case or not.

Q. But if that data exists would it be of interest to you as a physician and scientist?

A. It would be of interest. But again, I don't know if that data can be extrapolated. Just as an example of what I mentioned in rabbits because I don't know if it's of the same histological.

I think if you are looking at drug studies as far as physiologic responses, if you are looking at devices as far as safety of devices, that I think you can look at more easily. But as far as a study like, when you are looking at a totally different biological system, I don't know if that data could be extrapolated to humans or not.

Q. You simply don't know?

A. And I don't know the results, whether they're pro or con, that you are discussing. Whichever they are, it would bother me to look at

Page 270 that data not knowing if, with a different specie,

if that can be extrapolated.

Q. Assuming that there have been studies on a number of species — and indeed, strains of species — would that data be of interest to you to comb through to see if there were animal models used that you think would be extrapolable to the human situation?

MR. MIKHAIL: I object.

THE WITNESS: Yeah.

MR. MIKHAIL: You have asked that many different ways and he's answered it.

MR. ANDRADE: Well, I've asked the question many different ways but I'm not sure I've got an answer as to whether or not that information would be of value to Dr. Whittle in determining his position on causation. He's said that he's not familiar with those studies; therefore, it's difficult to ask him

MR. MIKHAIL: If you don't get the answer you want, that's not the standard, that's not the test.

I think he's answered to the best of his ability as to whether or not -- as you

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Page 271 asked him -- whether they would be of interest to him and I think he qualified as to he would have to know more about the specifies and the details and that sort of thing.

MR. ANDRADE: That's fine. Let me just ask a couple of questions without specifics. MR. MIKHAIL: If you could ask them in a different way that would put an end to it.

BY MR. ANDRADE:

Q. You have rendered your opinions in this case without regard to animal inhalation data; is that correct?

A. That's correct.

 Q. You have rendered your opinions in this case without any analysis of any animal experiments involving individual constituent of cigarette smoke; is that correct?

A. That's correct.

Q. You have just not listed that literature at all; is that correct?

A. That's correct.

MER. ANDRADE: All right.

Can I ask how much time we have on the tape? I might be able to give an estimate of

when we might be finished.

THE VIDEO TECHNICIAN: About an hour and five minutes.

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BY MR. ANDRADE:

Q. Dr. Whittle, do you know what an intervention trial is?

A. I'm not familiar with that term. if you could explain that to me.

Q. Do you know the type of epidemiological study that's termed an "intervention trial"? Do you know what kind of study that is?

A. I would presume that if you do some intervention of removing some factor or treating some factor to see if it changes the outcome. Is that what you are referring to?

Q. Yes. Are you aware of any intervention trials concerning cardiovascular disease?

A. Yes, I am.

Q. And could you identify those for me.

These are -- the studies that I'm more familiar with are those with relationship to cardiovascular mortality and even noncardiovascular mortality related to hypercholesterolemia. There's been some landmark studies in those that have been done recently.

There are some other studies with drugs 2 such as beta blockers in people post heart attack 3 that have shown reduced risk of sudden death. 4 There's also studies that have been done with some of the so-called Ace Inhibitors, so, yes, I am 5 6 familiar with those in those fashions. 7 Q. Are you aware of any intervention 8 trials that have looked at cigarette smoking and 9 cardiovascular disease? 10 A. No, I am not. Q. So, as you sit here today, you can't 11 12 identify any intervention trials that have looked at 13 groups where one group has had the level of cigarette smoking reduced, the other group was left 14 15 its usual, that has followed the two groups to 16 observe outcomes in cardiovascular disease mortality? 17 18 A. That's correct. 19 Q. Would this be information, if such 20 studies exist, that would be of interest to you as 21 an expert in formulating your opinion as to whether 22 or not cigarette smoking causes heart disease? 23 A. Yes. Again, I would have to look at

the study and evaluate the science. And if that was

appropriate, I would be more than happy to look at

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it. 2 Q. So at least you would find this information of interest --A. Yes. Q. - depending upon your assessment of its quality -A. That's correct. 8 O. — and scientific merit? 9 MR. ANDRADE: We can go off the record? 10 (Thereupon, a discussion was held off 11 the record.) 12 BY MR. ANDRADE: 13

Q. Dr. Whittle, have you ever heard of the 14 "Multiple Risk Factor Intervention Trial" conducted 15 with support by the National Heart, Lung and Blood 16 Institute? 17

A. Yes, I am.

Q. What is your knowledge of that study? Can you describe it for me, please?

A. Again, I would have to have the original papers right in front of me in order to know the specifics, but it was a study that looked at the various risk factors in the development -- I don't recall if it was an interventional study exactly. It may have been, but I would have to look

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Page 275 at some of the specifics. I am aware of the study. Q. Right. You don't recall what risk factors were evaluated in that study? 3 4 A. That's why I would have to look at the 5 original. 6 Q. Do you recall the results of those 7 studies? 8 A. That's why I would have to look at the 9 original paper. 10 Q. You don't recall the results as you sit 11 here today? 12 A. Not specifically, because I see so many 13 of those studies, particularly over the last few months, that I would have to go back and look at 14 15 that one specifically. 16 Q. Do you know if in that study the 17 intervention group significantly reduced its smoking 18 compared to the usual care group? 19 A. I would have to look at that data. Q. You have no recollection of the 20 21 specifics of the study? 22 Not specifically. 23 Q. Do you consider the MRFIT study to be 24 an important piece of epidemiological work in the

area of smoking and cardiovascular disease?

Page 276 A. Again, what I would have to do is to go back and look at the specifics of the paper, knowing when it was written, what was going on at the time, and what the data showed.

Q. All right. But you said you were aware of the study, correct?

A. Yes.

Q. You don't need to go back and look at the paper to answer the question: Do you consider it to be an important study in the field of cardiovascular disease and cigarette smoking?

 A. Again, I would have to go back and look and see what that data showed exactly. And then I can tell you in the context of the time in the present if it's important or not.

Q. Do you recall if it was a major study?

A. It was a very major study.

Q. A very important study?

A. It's a very major study. But again, I would have to go back and evaluate the data in the context of today's data, and see, is it important and is it meaningful?

Q. But as an expert, offering your expert opinions here today, you have no recollection of any details of what you would refer to as a major study,

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Page 277 the MRFIT study? A. It's an older study, and rather than misspeak I would rather go back and look at that data before I said anything. Q. Do you know when it was conducted? Can you give me a time period? A. That's why I was making the comment that I would need to look to see when it was done and how it was done, so -Q. You are not relying on the results of the MRFIT study at all in providing your expert testimony here today? A. No, I'm not. Q. Are you familiar with the U.K. Whitehall Study? A. No, I am not. Q. Are you familiar with the Intervention Trial conducted in Norway that's commonly referred to as the Oslo Study? A. Was that the original Oslo Heart Study? Q. The intervention trial conducted in Norway.

A. Which one?

Q. I'm asking you. Can you name more than

one? How many studies are you familiar with?

A. There are several that have been done in Norway. Is this the Oslo Heart Study? Do you know what the date on that was?

Q. I don't have that information with me, I'm afraid.

A. If you are referring to the original Oslo Heart Study, that was looking at the effect of lowering the cholesterol on coronary mortality, and there were some problems with that study at the time because of the drugs that were available at the time, if that's the one you are referring to.

Q. Do you know if the MRFIT study is still continuing today?

A. Again, as I mentioned to you, I would have to go back and I would have to look at that. I do not know.

Q. You don't know? A. No, I don't.

Q. Are you familiar with the World Health Organization's European Collaborative Study which was an intervention trial looking at risk factors for cardiovascular disease and cardiovascular disease outcomes?

A. I may be familiar with some of their data, but I don't remember the study specifically.

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Page 279 Q. You have no specific recollection of that? 2 That's correct. 3 Q. Are you familiar with the Intervention Trial looking at cardiovascular disease risk factors and cardiovascular disease outcomes that is commonly referred to as the Helsinki Study? 7 8 A. I am vaguely familiar. Again, I am 9 vaguely familiar with it. 10 Q. But you recall no specifics? A. I would have to go back and look at the 11 paper to get very specific.
Q. All right. You couldn't discuss the 12 13 basic design of the study here today? 14 15 A. No. Q. And you couldn't discuss the major 16 findings of the study? 17 18 A. No. If I went back and looked at the paper I could. 19 Q. How about the Goteborg, 20 G-O-T-E-B-O-R-G, Study in Sweden, which was another 21 cardiovascular disease intervention trial, are you 23 aware of that study? A. I am aware of it. But again, if you 24 had wanted me to review these, I would have been

glad to have done so. But rather than misspeak, I'm not going to go back and comment on something I haven't looked at for a number of years.

Q. So, once again, you wouldn't be able to discuss even the major findings?

A. I would not even attempt to unless I reviewed those recently. I have read all of those original reports at one time, but that's been quite some time ago, so I don't think it's fair for me to comment on those unless I have reviewed those recently.

Q. Do you know when the Goteborg Study was conducted?

A. No, I don't.

Q. The Helsinki Study?

A. Sir, I have just mentioned that I would have to go back and look and see when all of those studies have been done.

Q. I'm just asking you if you know when that study was conducted.

A. No. I've already answered that.

Q. What about the WHO European Collaborative Study, do you know --

A. I've already answered that,

Q. The Whitehall Study?

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3	STATE V AMERICAN TOBACCO 04-14-97Conde	ense	it" JAMES L. LITTLE, M.D. VOL 1 &
Γ	Page 281	T	Page 28
1	1 A. I've already answered that.	1	depends upon if you are looking at a population,
1	2 Q. And your answer is no, you don't know	2	say, where the incidence of coronary disease, for
	3 when it was conducted?	3	example, is very high, then that may be that may
	4 A. That's correct.	4	be a valid statement.
ı	5 Q. Dr. Whittle, let me read a statement to	5	If you are looking at a group where the
1	6 you and ask you if you agree with this. And I'm not	6	incidence of coronary disease is very small or if
1	7 quoting from a study.	7	the population sample is very small, that data may
1	8 "Randomization means that	8	not be applicable. That's why you have to examine
	9 participants in the study are randomly	9	each study on its own merit.
1	0 assigned to an intervention group and	10	Q. Would you agree with that statement, if
	to a control group. The intervention	11	you had a sufficient sample size, say, the magnitude
	2 group received efforts to reduce risk	12	of 12,000 individuals?
1	factor levels; the control group does	13	A. Yes. If the incidence of the disease
	4 not. Since which subjects are assigned	14	that you were looking for was significant in that
	5 to each grouping is determined	15	population, then, yes, that would be significant.
1	6 randomly; i.e., simply by chance, the	16	Q. Again, the statement I read
4	7 two groups would be expected to be	17	specifically stated coronary heart disease.
	8 similar at the start of the study.	18	A. That should be sufficient.
1	9 Thus any subsequent differences in CHD	19	Q. Is coronary heart disease the major
	mortality or incident rate can more	20	cause of death among nonsmokers?
2		21	A. I've really never looked at it from
	2 different ways the groups were	22	that viewpoint, so I can't answer that.
2		23	Q. So you don't know if that's the most
2		24	common cause of death among nonsmokers?
2	5 A. And that could be the case, but it	25	A. I've never been asked that question in

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Page 283 that fashion so I really can't answer. Q. Do you know what percentage of people 3 who -- of the people who die every year in the U.S., 4 what percentage of those people die of some form 5 cardiovascular disease? 6 A. It's the leading cause of death, but 7 what percentage that is, I don't know. 8 Q. Could you give me an estimate or --9 A. No. I would not even begin to. 10 Q. -- you just don't have that information? 11 11 12 Do you follow the literature in the 12 13 cardiovascular disease area very closely? 13 14 A. Reasonably closely. 14 15 Q. Could you tell me roughly when was the 15 16 last time you saw a study -- excuse me -- a 16 17 scientific paper, journal or article published on 17 18 the basis of MRFIT, the MRFIT study? 18 19 A. I've seen papers within the last few 19 20 months that have gone back and referenced to that 20 21 with some of the interventional trials on 21

hypercholesterolemia. But as far as which articles

Q. In terms of articles that came from the

MRFIT study itself, do you recall the last time you

specifically, I can't recall.

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Page 284 saw any article reporting results from the MRFTT Study?

A. I don't recall.

Q. How about the Whitehall study from the U.K.?

A. As I've said, I don't recall.

Q. Doctor, I think earlier you mentioned that the Braunwald text was a text, while you wouldn't consider it authoritative, you would consider it to be an excellent text; is that correct?

A. That's correct.

Q. Okay. In fact, you wrote in an article a number of years ago, I believe, that this text, an article that was written in 1982, was an excellent cardiology text. Would you still agree with that?

A. It's an excellent text, yes.

Q. Would you go to Braunwald's as a source of information if you were looking for reliable information in the field of cardiovascular disease?

A. If I was going to -- it depends upon what I was looking for. If it was something new, I would not. I would go more to a computer literature search because it would be newer. If it was something old, such as "Primary Tumors of the

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	Page 285		Page 286
1	Heart," or something like that, that has changed	1	"In the late 1940s and early
2	very little, then I might go back and look.	2	1950s, several studies of free-living
3	Q. But your characterization of the	3	populations were begun to discern the
4	Brannwald text as being an excellent text would at	4	factors associated with the occurrence
5	least be a fair characterization as of the edition	5	of coronary heart disease and how the
6	that you were speaking of when you wrote this	6	disease evolves and terminates in a
ž	article?	7	total population. Clinical impressions
Ŕ	A. Yes.	8	were soon confirmed: Coronary heart
١٥	(Thereupon, the document was marked	9	disease did not occur randomly in the
10	Defendant Lorillard's Exb. No. 14 for	10	population. Its rate of occurrence
11	Identification.)	lii	varied greatly according to demographic
12	BY MR. ANDRADE:	12	factors such as age, race and sex.
13	Q. I'd like to mark what is Defendant's	13	Personal attributes detectable by
14	Exhibit No. 14, okay, Doctor, and give that to you.	14	simple medical examination: high serum
15	And this is a chapter from a book entitled "Heart	15	cholesterol, high blood pressure,
16	Disease, a Textbook of Cardiovascular Medicine."	16	hyperglycemia and obesity were found to
17	A. Uh-huh.	17	increase the frequency of the disease.
18	Q. Edited by Eugene Braunwald.	18	"Personal habits, which the
19	A. 1980.	19	patient could easily recognize
20	Q. 1980. And I'd like to direct your	20	themself, cigarette smoking, lack of
	attention to page 1247.	21	exercise, nutritional habits, were also
21	A. Okay.	22	investigated. More recently, some
22 23	Q. And the upper left-hand corner, the	23	specific environmental hazards: carbon
24	first column, if I could read that to you and ask	24	disulfide, oral contraceptives, have
25	you if you agree with it.	25	been associated with increased
23	you if you agree with it.	<u> 1</u>	0441 -0041444 11141 11141 -044

			B 800
	Page 287		Page 288
1	Occurrence of CHD. Underlying these	1	by simple medical examination: high
2	factors, familial and genetic effects	2	serum cholesterol, high blood pressure,
3	are believed to play an inceptive role	3	hyperglycemia and obesity were found to
4	in concert with their complex	4	increase the frequency of the disease"?
5	interrelationships with social and	5	A. I would agree with that.
6	psychological factors."	6	Q. Would you agree with the sentence:
7	That's a long statement. Would you	7	"More recently, some specific
8	agree with that?	8	environmental hazards: carbon
9	A. I don't know what some of this means.	9	disulfide, oral contraceptives, have
10		10	been associated with increased
11	is. I've never seen the word "inceptive" in my	11	Occurrence of coronary heart disease"?
12	life.	12	A. Are you asking if I would agree with
13	Q. So you wouldn't have a personal	13	that?
14	definition for it if you haven't encountered the	14	Q. Yes.
15	word before?	15	A. I know absolutely nothing about carbon
16	A. Do you know what it is, because I have	16	disulfide. I don't know that that's really panned
17	no idea?	17	out. And also with regard to oral contraceptives,
18	Q. I'm afraid I don't.	18	there may be some increased incidence of coronary
19	A. Now, these statements, I think, are so	19	thrombosis but not necessarily coronary
20	general it's difficult to really say much. But some	20	atherosclerosis.
21	of this I just don't quite understand what their	21	But you also have to remember that this
22	point is.	22	was published in 1980, which probably means that
23	Q. Would you agree with the sentence in	23	some of the data in here is three years old, so
24	that statement:	24	we're looking at 20-year-old data. And so I'm
25	"Personal attributes, detectable	25	thinking it may have been very appropriate at the
	*** No	tes '	**

time, but I think at this time it's not quite up-to-date.

Q. Are you aware of subsequent literature in the area of oral contraceptives associating them with increased risk for coronary heart disease in

A. With coronary thrombosis but not with development of atherosclerosis. And the carbon disulfide I'm not familiar with at all.

Q. Okay. Can coronary heart disease result from thrombosis as well as atherosclerosis?

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Did you want this back?

Q. Yes, please. Put it in here. Earlier, Dr. Whittle, I asked you a series of questions about ascertaining the biological cause of a disease of the circulatory system by virtue of examining tissue. And I asked that question in the context of multiple risk factors.

If you have one of the patients that you referred to later, who only had smoking as a risk factor in his background and who had -- that individual suffered a heart attack, could you look at that heart and identify any marker for cigarette

Page 290 smoking that would allow you to say, Here is biological demonstration that cigarette smoking causes heart attack?

A. I think just as I said earlier, the answer would be no. But again, though, we're looking at the final common pathway. And I think we can't really make any comments about that.

If there are no other known risk factors, we have to look at the whole system in totality. And in that case, yes, we can say that. But as far as looking at anything pathologic and say is that a marker, the answer is no.

Q. Okay. I didn't ask the question with respect to individuals who only have cigarette smoking as a risk factor in their background, but with respect to aortic aneurysm or coronary heart disease or peripheral vascular disease, you couldn't look at the diseased tissue, you couldn't look at the atherosclerotic build up and find any marker that have indicated it was cigarette smoking that caused that disease; is that correct?

A. That's correct. I think we've said the same thing earlier also.

Q. All right.

MR. ANDRADE: If we can go off the

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record for a minute.

(Thereupon, a discussion was held off the record.)

(Thereupon, a recess was taken.)

BY MR. ANDRADE:

Q. Dr. Whittle, are you familiar with the Framingham Study?

A. Yes, I am.

Q. Isn't it true, Dr. Whittle, that the data from the Framingham Study reported no association between angina and cigarette smoking?

A. I don't recall the specifics over the years to be able to comment on that.

Q. But you have no recollection of the major findings of that study?

A. Yes, I do, some of the major findings.
Q. What, in your opinion, are some of the major findings of the Framingham Study?

A. The relationship between hypercholesterolemia and coronary disease and smoking and coronary disease.

Q. All right. So the Framingham Study, in your opinion, found that high cholesterol levels was associated with the development of coronary heart disease?

Page 292 A. Again, I would have to go back and review the last data. That data is still coming out from the Framingham Study. But before making any specific comments, I would almost have to review some of the recent data.

Q. But you have no, as we sit here today, no recollection of their findings with respect to cigarette smoking and angina?

A. Again, I think I've read just about every report that's come out of Framingham, but to get specific I would have to go back and review those.

(Thereupon, the document was marked Defendant Lorillard's Exb. No. 15 for Identification.)

BY MR. ANDRADE:

Q. Let me hand you what's been marked as Defendant's Exhibit 15. And for the record, it's an article entitled, "The Negative Association in Women Between Cigarette Smoking and Uncomplicated Angina Pectoris in the Framingham Heart Study," by Carl Seltzer from the "Journal of Clinical Epidemiology."

And Doctor, if I could direct your attention to the second half of the abstract. I'd like to read it to you and see if you agree with it.

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JAMES L	LITTLE, M.D. VOL 1 & 2 Conde	DSC	IT STATE Y AMERICAN TUBACCO U4-14-9/				
	Page 293		Page 294				
1	"The published declarations by	1	lend support to the belief held by some				
2	Framingham investigators of an absence	2	that smoking enhances the degree of				
3	of association between cigarette	3	coronary atherosclerosis."				
4	smoking and angina pectoris in	4	Do you agree with that statement?				
5	Framingham women is a failure to	5	A. I don't know. And let me say why I				
6	publicly recognize the distinctive	6	don't know. I would have to go back and look and				
7	negative association present in the	7	sec. Because of the relationship between cigarette				
8	Framingham female data. The Framingham	8	smoking and angina pectoris, there have been a				
9	data on the relationship of smoking to	9	number of studies done over the years in which				
10	angina incidence is clearly a variance,	10	angina pectoris was assumed to be a manifestation of				
11	with the Surgeon General's sketchy	11	coronary disease but without objective findings.				
12	finding of an inconsistent positive	12	There are some chest pain syndromes				
13	association for men and an uncertain	13	that may mimic angina dramatically. Unless there is				
14	relationship for women.	14	some objective data to show that that was angina and				
15	"It is suggested that special	15	not just a chest pain syndrome that was similar to				
16	attention should be directed to these	16	angina, I would need to know. Otherwise, you're				
17	results of the Framingham data because	17	drawing conclusions about something that may be				
18	of the preeminence of Framingham	18	invalid. Your assumption is that the angina				
19	material world wide because angina	19	pectoris is coming from coronary disease. But				
20	pectoris is the most common	20	unless that's substantiated in some fashion, that				
21	manifestation of coronary heart	21	may not be a valid assumption. So I would have to				
22	disease, because it will improve the	22	look at the data more specifically and the methods.				
23	'conventional wisdom' on the subject,	23	Q. Well, what are some of other sources of				
24	and because the negative relationship	24	angina pectoris?				
25	found for Framingham women does not	25	A. Well, one of the things you have to				
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Page 295 also consider is that sometimes esophageal spasm can mimic angina precisely. Specifically in women there's a problem called Syndrome X which there is two different Syndrome X's, one of which is angina with small coronaries which does not have the same prognosis.

So if someone has angina, is this truly angina? Is it angina due to epicardial coronary disease? Is it angina due to small vessel coronary disease? Is this esophageal reflux?

The problem is, if you have a hodgepodge of diagnoses that you are calling angina and then you are trying to correlate an association with cigarette smoking and that, unless you've got objective evidence by either stress testing or coronary angiography, that may not be a valid assumption.

Q. Because it may not be angina pectoris as defined in a more precise sense?

A. No, no. Angina pectoris is a clinical diagnosis but it needs to be substantiated to see if its on the basis of a problem with the coronary circulation.

Q. So the pain that would be defined by angina pectoris may have some other sources? A. That's correct.

Q. I didn't realize the confusion.

A. And that's why -- if -- there was a study that was done many years ago about looking at aspirin. And there was a major problem with the study because people were lumped into the diagnosis of having angina pectoris who were enrolled in the study, one of whom was my brother-in-law at the time and who actually had a collapsed lung.

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So the problem is that when you start making associations without objective findings, you can really get into trouble. So I would need to know within the methods if it was truly established as being on the basis of coronary disease before I would accept this as being valid.

Q. Okay. All right. Have you any opinions on whether or not angina pectoris is associated with cigarette smoking in the females in your particular practice?

A. Again, I can maybe make some comments about an association between angina -- I mean between coronary disease and smoking, but not necessarily angina and smoking.

Again, because sometimes the diagnosis of angina -- as you brought up yourself earlier --

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	Page 297	7	Page 2	98
1	if someone comes into the office and says, I have	1	MR. ANDRADE: That, I would imagine, is	
2	angina, then I'm going to question if that's really	2	the chapter title, "Coronary Health	
3	angina or not.	3	Promotion: An Overview." And then	
4	Q. I see.	4	"Prevention of Myocardial Infarction" would	
5	A. And that's really part of the problem.	5	be	
6	Q. Okay.	6	MR. MIKHAIL: - the book. And the	
7	Doctor, I would like to read a	7	author is C.J. O'Donnell?	
8	statement to you, and unfortunately I don't have the	8	MR. ANDRADE: CJ. O'Donnell.	
9	article	9	MR. MIKHAIL: I'm sorry. I didn't mean	
10	A. Are we done with this?	10	to interrupt; I wanted to write it down.	
11	Q. Yes.	11	MR. ANDRADE: That's quite all right.	
12	because the Federal Express failed us	12	BY MR. ANDRADE:	
13	and the article that was supposed to be sent did not	13	Q. Doctor, beginning with, "Controlled	
14	arrive. But I will give you the citation. The	14	trials, preferably with randomization,	
15	citation is from an article entitled, "Coronary	15	have become the gold standards for	
16	Health Promotion: An Overview," appearing in the	16	proof of a benefit from preventive or	
17	journal, "Prevention of Myocardial Infarction."	17	other interventions. And large scale	
18	A. That's the name of the journal?	18	trials allow reliable comparison of	
19	Q. Yes. I stand corrected. It's actually	19	benefits versus risks. Proper	
20	a book, so it's actually a book. The first author	20	randomization is a sample of adequate	
21	is C.J. O'Donnell. So let me read it to you and ask	21	size, virtually eliminates the chance	
22	if you agree with it.	22	of baseline differences among treatment	
23	MR. MIKHAIL: Let me make sure I get	23	groups will play any meaningful role in	
24	this. The book is called "Coronary Health	24	the study outcome, and blinding, if	
25	Promotion"?	25	possible, further reduces the risk that	
	*** No	otes '	***	

3	differed after randomization. Thus the quality of evidence in preventive	3 4	easier when it's a paragraph long. THE WITNESS: Particularly at this
5	interventions is strongest if derived	5	hour.
6	from properly designed, randomized	6	MR. ANDRADE: We'll mark this as
7	controlled trials. Less strong if	7	Defendant's Exhibit No. 16. Again, it would
8	derived from cohort or case controlled	8	be a chapter entitled "Coronary Health
9	studies and weakest if derived from	9	Promotion: An Overview," from a book
10	descriptive studies or from the	10	entitled "Prevention of Myocardial
11	clinical experience of one or	11	Infarction," first author, C.J. O'Donnell.
12	a few experts."	12	(Thereupon, the document was marked
13	MR. MIKHAIL: Would you like to have	13	Defendant Lorillard's Exb. No. 16 for
14	that in front of you before you ask any	14	Identification and subsequently replaced with
15	questions?	15	the revised copy.)
16	THE WITNESS: Yeah.	16	MR. MIKHAIL: Take a moment to look at
17	MR. ANDRADE: I'll be glad to do that.	17	it if you need to.
18	MR. MIKHAIL: It's hard to just hear.	18	THE WITNESS: There is one
19	MR. ANDRADE: Is there any need to mark	19	typographical error in here. It doesn't make
20	it as an exhibit because I won't have a copy?	20	any sense. It says, "Proper randomization as
21	I'll have to remove	21	a sample of adequate size virtually
22	MR. MIKHAIL: I'll leave that up to	22	eliminates the chance that baseline
23	you. Just wanted to be able to see it.	23	differences"
24	MR. ANDRADE: Bear with me as I remove	24	That doesn't make any sense, so I don't
25	information. I'll do this and I'll probably	25	know if this was transcribed properly.

BY MR. ANDRADE: 1 Q. I'm not sure, Dr. Whittle. 2 A. That kind of throws off the --3 Q. Does that make it impossible for you 5 to -6 A. Yes. That makes no sense at all. 7 O. - offer as to whether you agree to it or not? 8 9 A. Yes. MR. MIKHAIL: Is that going to be your 10 question, as to whether it he agrees with the 11 12 paragraph or not? 13 MR. ANDRADE: Yes. THE WITNESS: I can't say that because 14 15 I think it's been transcribed improperly. 16 BY MR. ANDRADE: Q. Maybe I can check on whether the 17 transcription is accurate or not and then ask you 18 19 some other questions on one last area. Your expert disclosure indicates that 20 you are going to be offering expert opinions on the 21 ordinary costs associated with the various 22 cardiovascular diseases that we've discussed today. 23 Can you tell me what your opinions are 24

going to be and the bases of those opinions, please?

A. Really the only thing I think I have to add in that view is the rough cost of intervention, such as catheterization, angioplasty, heart attack, bypass surgery on an individual patient because that's the data that I have in my head.

Q. Will your testimony be as to the market price, if you will, of the cost in this area for each of those procedures?

A. I would presume so.

Q. Will you offer testimony on the, perhaps, individual variation of costs based on other considerations?

A. I would presume so but I obviously wouldn't be the one asking the questions so that would be difficult for me to say.

Q. What opinions do you expect to offer in that regard?

A. If asked, I'll be glad to make some - Q. This is my opportunity, Doctor, to ask you what opinions you expect to offer at trial.

A. I think it would just be that if you ask me what is the cost of various interventions, I can tell you roughly what those are.

MR, MIKHAIL: Are you asking him what those are?

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MR. ANDRADE: I'm asking what opinions he expects to offer at trial.

BY MR. ANDRADE:

Q. And if I understand correctly, you are saying you will testify as to the costs of various procedures?

A. That would be all I would anticipate.

Q. So if I were to ask you what the cost of angioplasty is, you would respond by giving a particular dollar figure?

A. Yes.

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Q. Have you done any studies with respect to these health care costs?

A. No. This would be, again, just talking with patients and knowing about what costs run. Again, in today's managed care environment, that varies from person to person dramatically, but that's all. I've not done any cost analysis.

Q. So, again, your testimony would be limited to your clinical experience and offering, perhaps a range of prices for various procedures --

A. Right.

Q. — that you might conduct and others might conduct on cardiovascular diseased patients?

A. Right. And I think that would be a

very small part of what I was asked to do.

Q. Are you going to offer any opinions about differential costs between Medicaid patients and other patients?

Page 304

A. I would be happy to, if I was asked

Q. Do you expect to offer that kind of testimony on behalf of the State of Florida? Have you been asked to render opinions in that area?

A. No, I have not.

Q. So you don't expect to render opinions in that area?

A. If I was asked, I would be happy to within what I am able to, but I've not been asked.

Q. What I'm here to find out about is what opinions you expect to offer at trial. And that is not a function of what you might be asked.

But while you've been retained for this lawsuit, have the State of Florida attorneys asked you to offer opinions as to differential costs of procedures as between Medicaid patients and normal patients?

MR. MIKHAIL: Before you answer that, maybe this will make things clearer. If not, please feel free to ask the question again.

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	Page 305
1	Dr. Whittle is not going to be asked
2	and he is not retained to give opinions as to
3	what cardiovascular disease or coronary heart
4	disease costs the state taxpayers in Florida,
5	if that is what you are asking.
6	BY MR. ANDRADE;
7	Q. Yes. And I think you have answered
8	specifically answered this earlier but I want to
9	make sure, because I didn't ask you in the context
10	of your expert report, that your testimony won't be
11	tied to the bottleneck that will be at issue in the
12	case?
13	MR. MIKHAIL: It won't be. As to the
1	11-4'C J11 TT'-

calculation of damages, no, not at all. His testimony is strictly medical. And the ordinary costs which I tried to clarify this morning -- because it was unclear and I'll grant you that -- is costs he's familiar with as to how much does it cost to do an angioplasty. And to give an idea of what it costs to treat a patient with the various forms of cardiovascular disease that he encounters. It was not tied to the model, it isn't tied to the model, and he has no expertise and is not going to be offering

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Page 306 opinions as to what it costs the State of Florida to treat, from a taxpayer's money, public health care expenditures on cardiovascular disease. That is not what he's being offered for. BY MR. ANDRADE:

Q. Your testimony will be limited to providing a price list, if you will, based on your experience as a physician who either conducts certain procedures and charges a certain amount?

MR. MIKHAIL: And not only his but what the market is, and what's in the market. He knows what other -- that's our understanding. If I'm incorrect, you may correct me.

THE WITNESS: No. I would agree.

BY MR. ANDRADE:

- Q. You will offer testimony from the --I'm not sure if it's adequately or accurately characterized as opinion testimony, but you will offer fact testimony as to what you might charge, what colleagues might charge --
 - A. That's correct.
- Q. -- and also what a range of the charges might be given that managed care might pay differently than government and perhaps third-party

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	Page 307		Page 308					
1	private insurance?	1	that.					
2	MR. MIKHAIL: As counsel for the	2	MR. ANDRADE: I'll tell you what,					
3	plaintiffs, I think that's a very fair	3	Would it be acceptable, Charles, if what we					
4	characterization.	4	did was to obtain a copy of the original and					
5	MR. ANDRADE: And that will save us a	5	send it in and have that marked for the					
6	lot of time. If I may just check.	6	records? And it will indeed have the right					
7	MR. MIKHAIL: Okay.	7	text. And of course if somehow the text of					
8	BY MR. ANDRADE:	8	the original varies from the connection that					
9	Q. I think we have it. Will you allow me	9	we think will make this an accurate					
10	to make a correction to change the word "is" to "in"	10	translation, then the doctor can review the					
11	which I think	11	transcript and					
12	A. That makes sense. That's fine.	12	MR. MIKHAIL: I think that's the					
13	Because this made absolutely no sense the way it was	13	practical way to do it. You can ask him					
14	written.	14	assuming that the text appeared as it					
15	MR. MIKHAIL: Are we on the record? I	15	appeared with his correction, what your					
16	just want to make a very brief statement. I	16	opinion is about that. But again, we'll have					
17	have no objection to you asking him the	17	to check it and supplement the record.					
18	question or him answering, but I want to make	18	MR. ANDRADE: With that assumption, I					
19	sure he checked it against what actually	19	won't read the statement again. I just want					
20	appeared in the textbook as opposed to us or	20	to ask you if you agree with it and perhaps					
21	you changing wording in a paragraph.	21	you can give it back to me.					
22	But feel free to ask him questions but	22	MR. MIKHAIL: I'm not trying to be					
23	I do want the record to reflect I object if,	23	difficult. I just wanted to make sure.					
24	in fact, we're changing something in what, in	24	MR. ANDRADE: That's fine,					
25	fact, appeared in a textbook. I object to	25	MR. MIKHAIL: So you weren't hurt for					
